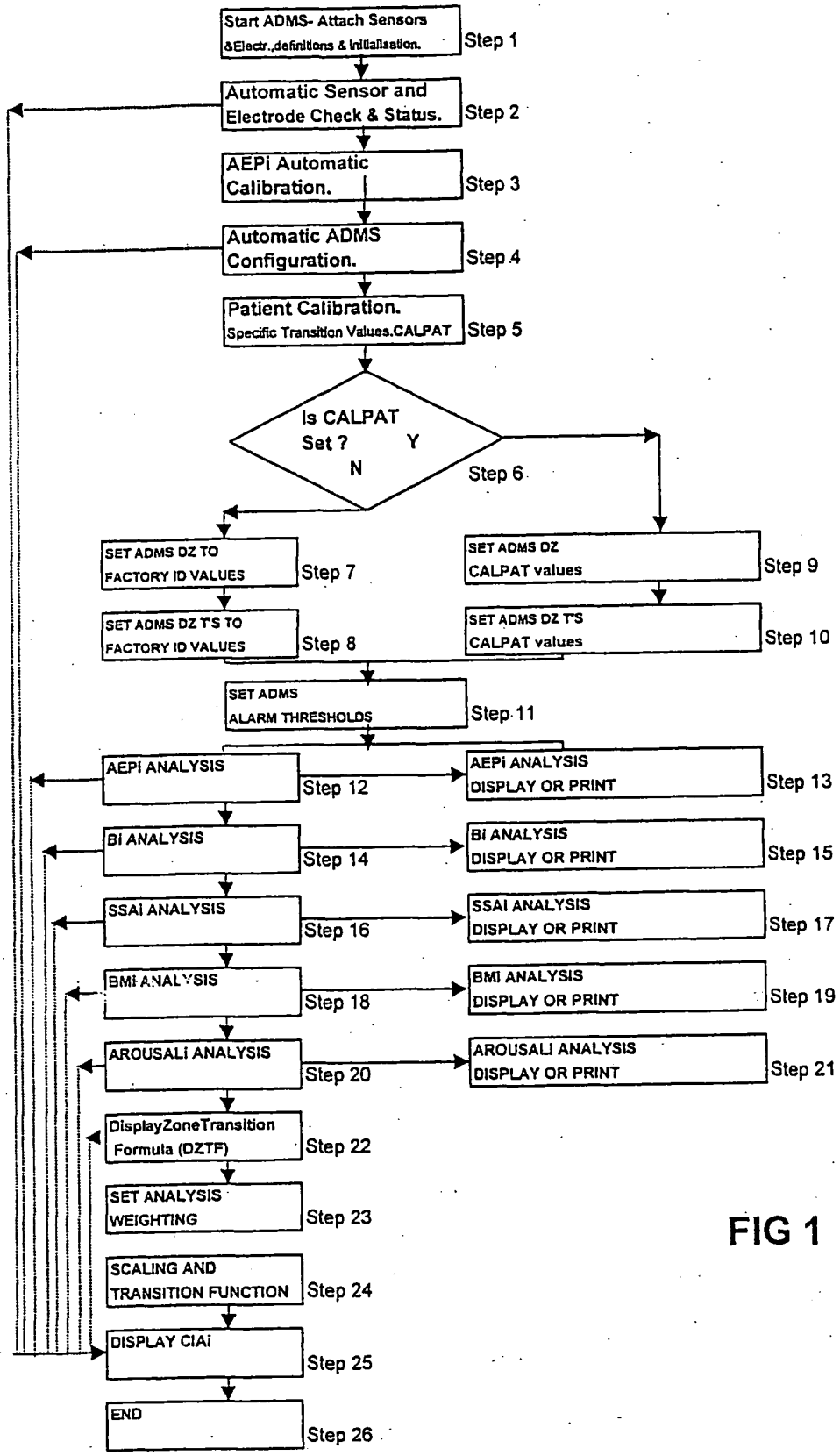

Start ADMS- Attach Sensors &Electr.,definitions & initialisation.
Step 1
Automatic Sensor and Electrode Check & Status.
Step 2
AEPi Automatic Calibration.
Step 3
Automatic ADMS Configuration.
Step 4
Patient Calibration. Specific Transition Values.CALPAT
Step 5
Is CALPAT Set ? Y N
Step 6
SET ADMS DZ TO FACTORY ID VALUES
Step 7
SET ADMS DZ TS TO FACTORY ID VALUES
Step 8
SET ADMS DZ CALPAT values
Step 9
SET ADMS DZ TS CALPAT values
Step 10
SET ADMS ALARM THRESHOLDS
Step 11
AEPi ANALYSIS
Step 12
AEPi ANALYSIS DISPLAY OR PRINT
Step 13
Bi ANALYSIS
Step 14
Bi ANALYSIS DISPLAY OR PRINT
Step 15
SSAi ANALYSIS
Step 16
SSAi ANALYSIS DISPLAY OR PRINT
Step 17
BMi ANALYSIS
Step 18
BMi ANALYSIS DISPLAY OR PRINT
Step 19
AROUSALi ANALYSIS
Step 20
AROUSALi ANALYSIS DISPLAY OR PRINT
Step 21
DisplayZoneTransition Formula (DZTF)
Step 22
SET ANALYSIS WEIGHTING
Step 23
SCALING AND TRANSITION FUNCTION
Step 24
DISPLAY CIAi
Step 25
END
Step 26

FIG 1

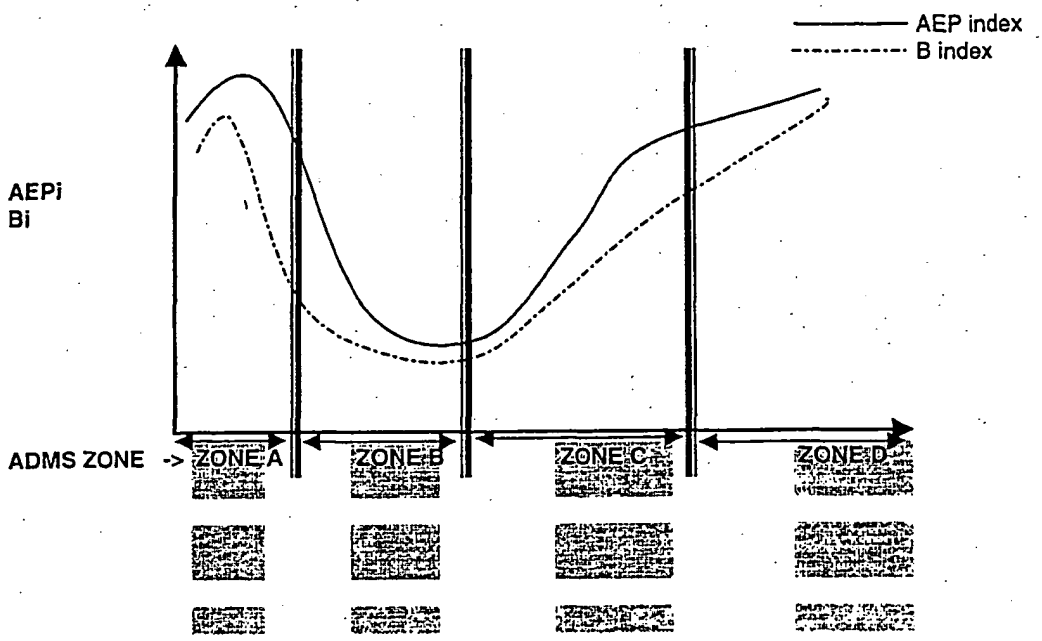


FIG 2

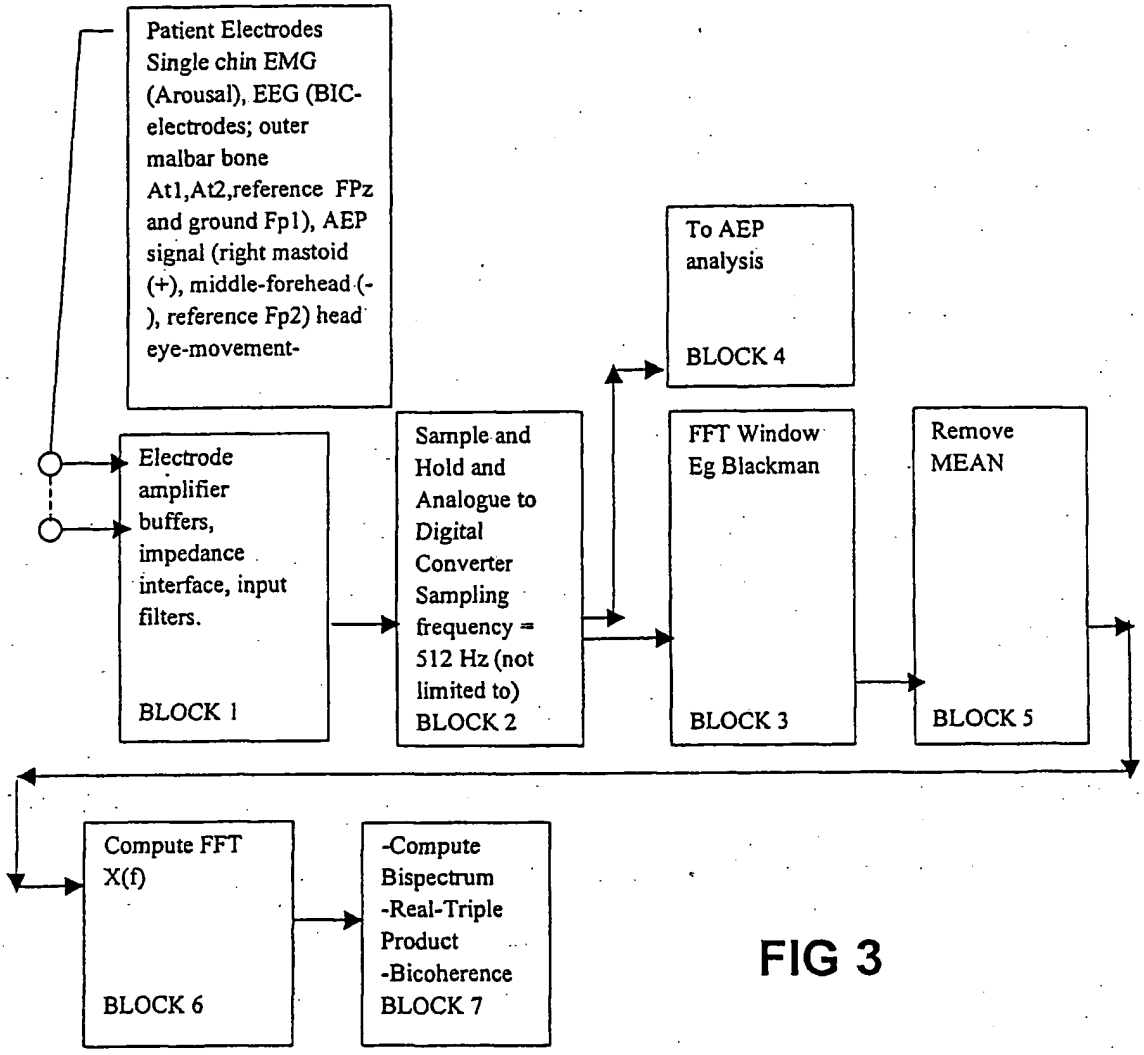

Patient Electrodes Single chin EMG (Arousal), EEG (BIC-electrodes; outer malbar bone At1,At2,reference FPz and ground Fp1), AEP signal (right mastoid (+), middle-forehead (-), reference Fp2) head eye-movement-
To AEP analysis
BLOCK 4
Electrode amplifier buffers, impedance interface, input filters.
BLOCK 1
Sample and Hold and Analogue to Digital Converter Sampling frequency = 512 Hz (not limited to)
BLOCK 2
FFT Window Eg Blackman
BLOCK 3
Remove MEAN
BLOCK 5
Compute FFT X(f)
BLOCK 6
-Compute Bispectrum
-Real-Triple Product
-Bicoherence
BLOCK 7

FIG 3

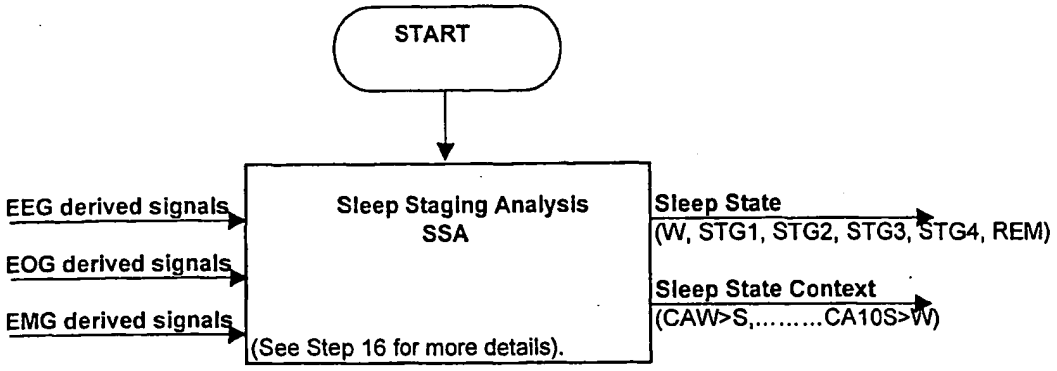

START
EEG derived signals
EOG derived signals
EMG derived signals
Sleep Staging Analysis
SSA
(See Step 16 for more details).
Sleep State
(W, STG1, STG2, STG3, STG4, REM)
Sleep State Context
(CAW>S,.....CA10S>W)

FIG 4

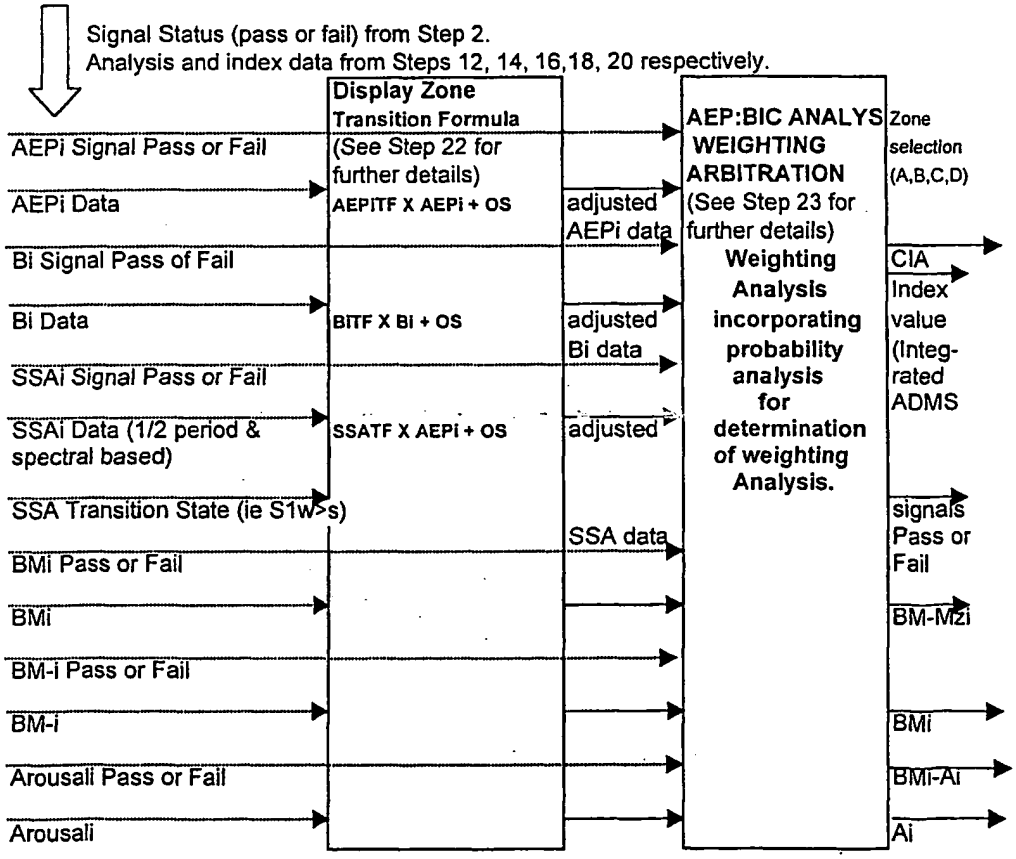

Signal Status (pass or fail) from Step 2.
Analysis and index data from Steps 12, 14, 16,18, 20 respectively.
Display Zone
Transition Formula
(See Step 22 for further details)
AEPi Signal Pass or Fail
AEPi Data
AEPITF X AEPi + OS
Bi Signal Pass of Fail
Bi Data
BITF X Bi + OS
SSAi Signal Pass or Fail
SSAi Data (1/2 period & spectral based)
SSATF X AEPi + OS
SSA Transition State (ie S1w>s)
BMi Pass or Fail
BMi
BM-i Pass or Fail
BM-i
Arousali Pass or Fail
Arousali
adjusted AEPi data
adjusted Bi data
adjusted
SSA data
AEP:BIC ANALYS
WEIGHTING
ARBITRATION
(See Step 23 for further details)
Weighting Analysis incorporating probability analysis for determination of weighting Analysis.
Zone selection (A,B,C,D)
CIA Index value (Integ-rated ADMS
signals Pass or Fail
BM-Mzi
BMi
BMi-Ai
Ai

FIG 5

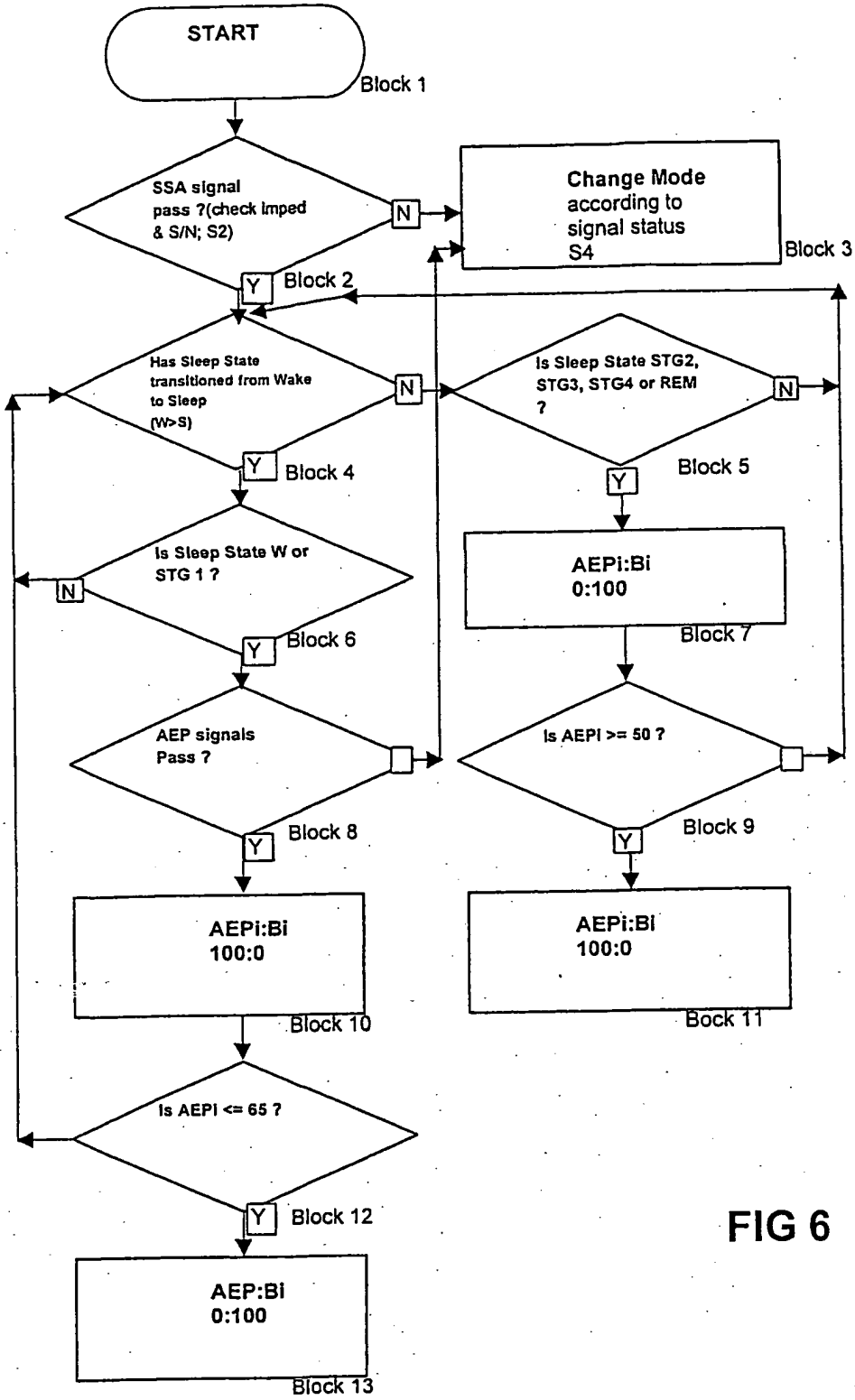

START
Block 1
SSA signal pass ?(check Imped & S/N; S2)
N
Change Mode according to signal status S4
Block 3
Y
Block 2
Has Sleep State transitioned from Wake to Sleep (W>S)
N
Is Sleep State STG2, STG3, STG4 or REM ?
N
Y
Block 4
Block 5
Y
Is Sleep State W or STG 1 ?
AEPi:Bi 0:100
N
Block 7
Y
Block 6
AEP signals Pass ?
Is AEPI >= 50 ?
Block 8
Block 9
Y
Y
AEPi:Bi 100:0
AEPi:Bi 100:0
Block 10
Bock 11
Is AEPI <= 65 ?
Y
Block 12
AEP:Bi 0:100
Block 13

FIG 6

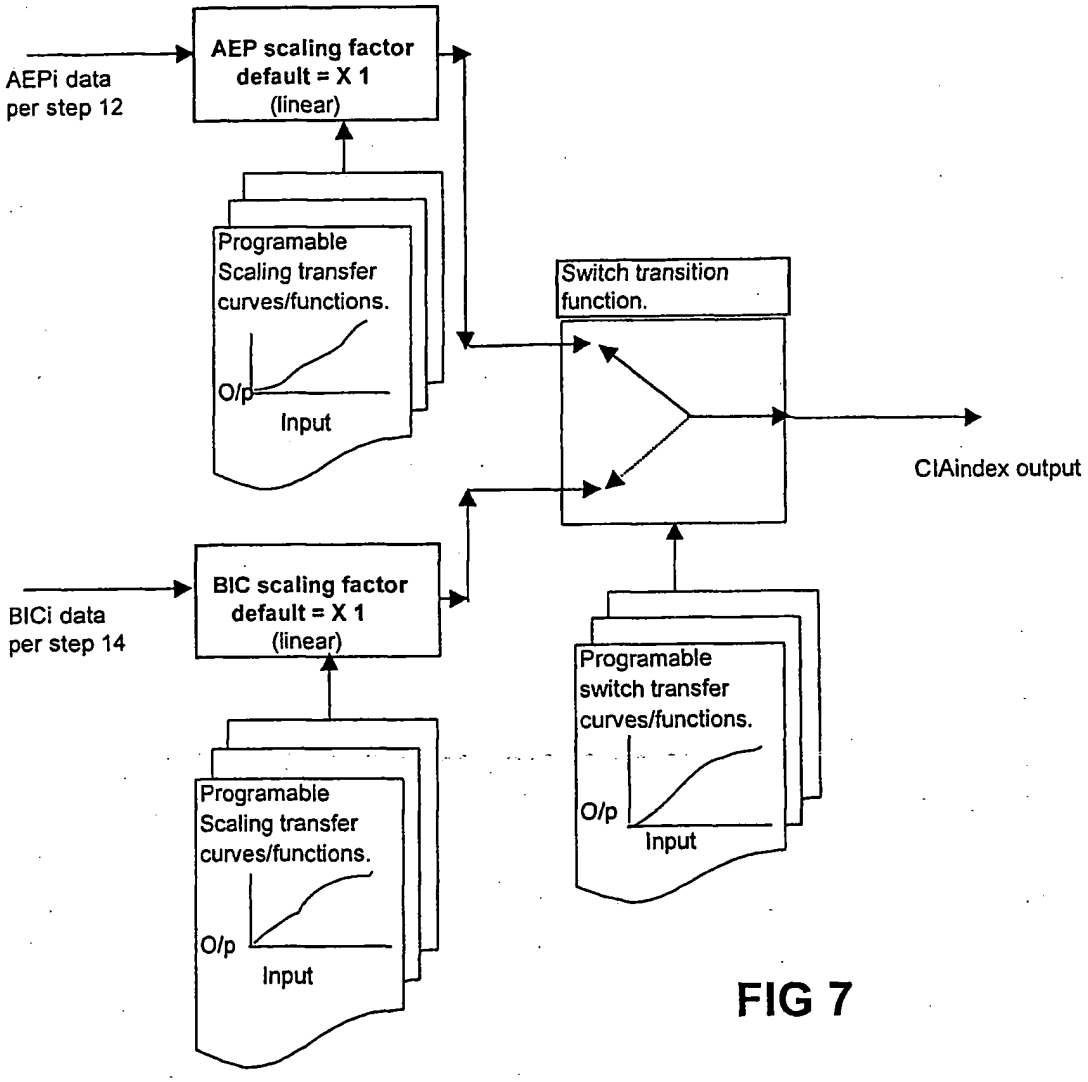

AEPi data
per step 12
AEP scaling factor
default = X 1
(linear)
Programable
Scaling transfer
curves/functions.
O/p
Input
Switch transition
function.
CIAindex output
BICi data
per step 14
BIC scaling factor
default = X 1
(linear)
Programable
switch transfer
curves/functions.
O/p
Input
Programable
Scaling transfer
curves/functions.
O/p
Input

FIG 7

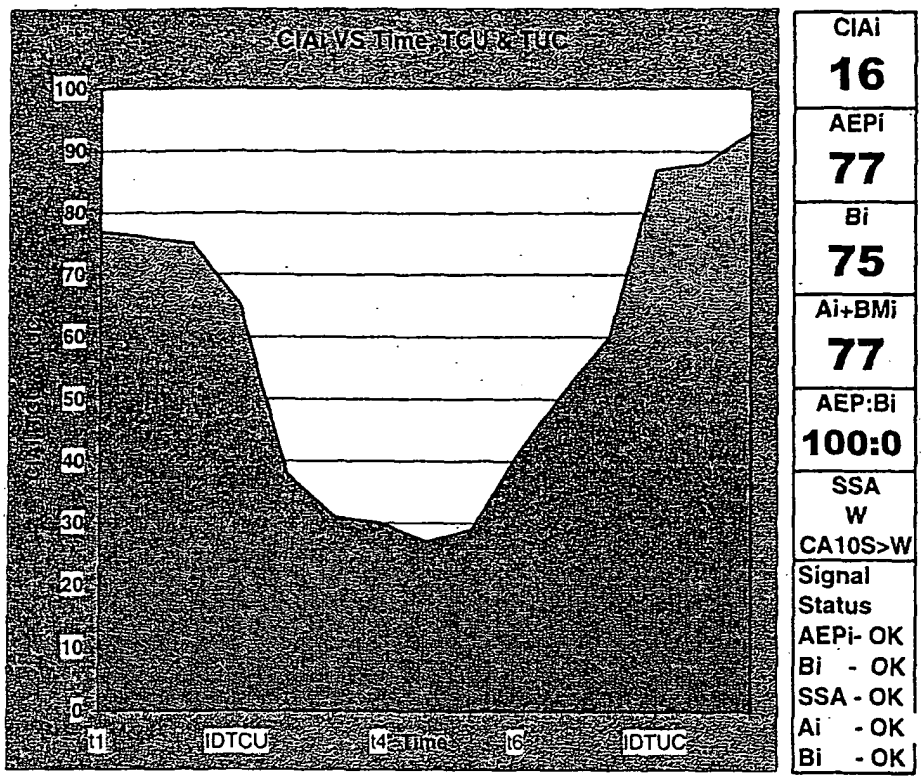

ClAi VS Time; TCU & TUC
100
90
80
70
60
50
40
30
20
10
0
t1
IDTCU
t4
Time
t6
IDTUC
ClAi
16
AEPi
77
Bi
75
Ai+BMi
77
AEP:Bi
100:0
SSA
W
CA10S>W
Signal
Status
AEPi- OK
Bi - OK
SSA - OK
Ai - OK
Bi - OK

FIG 8

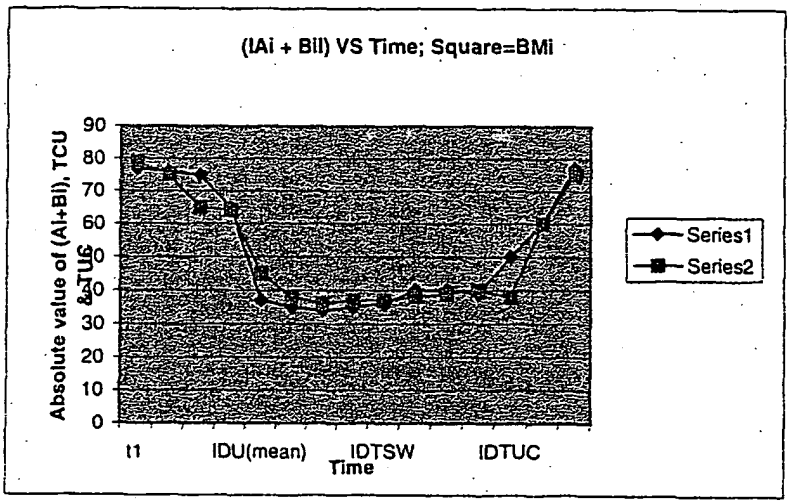

(IAi + BiI) VS Time; Square=BMi
Absolute value of (Ai+Bi), TCU &TUC
90
80
70
60
50
40
30
20
10
0
t1
IDU(mean)
IDTSW
IDTUC
Time
Series1
Series2

FIG 9

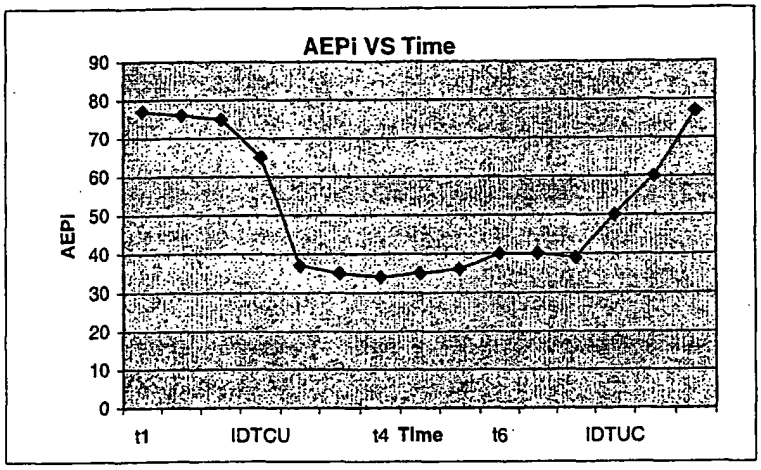

AEPi VS Time
AEPI
90
80
70
60
50
40
30
20
10
0
t1
IDTCU
t4 TIme
t6
IDTUC

FIG 10

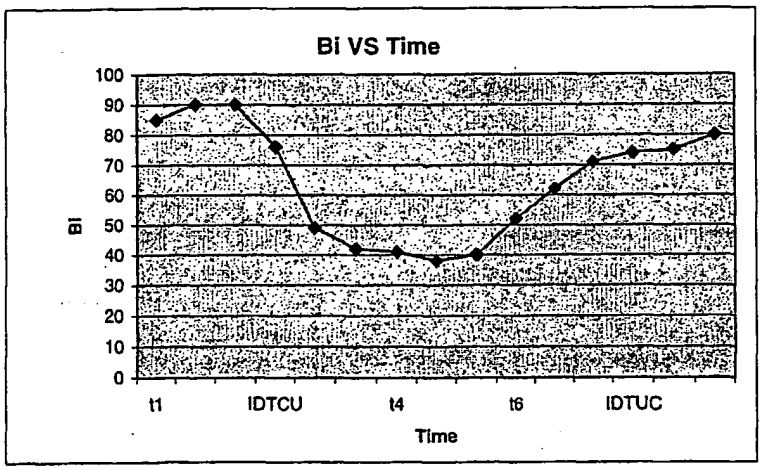

Bi VS Time
Bi
100
90
80
70
60
50
40
30
20
10
0
t1
IDTCU
t4
t6
IDTUC
Time

FIG 11

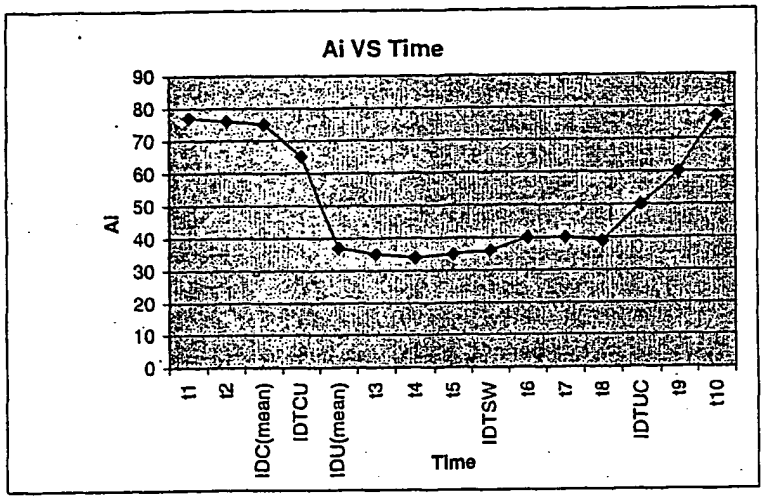

Ai VS Time
Ai
90
80
70
60
50
40
30
20
10
0
t1
t2
IDC(mean)
IDTCU
IDU(mean)
t3
t4
t5
IDTSW
t6
t7
t8
IDTUC
t9
t10
Time

FIG 12

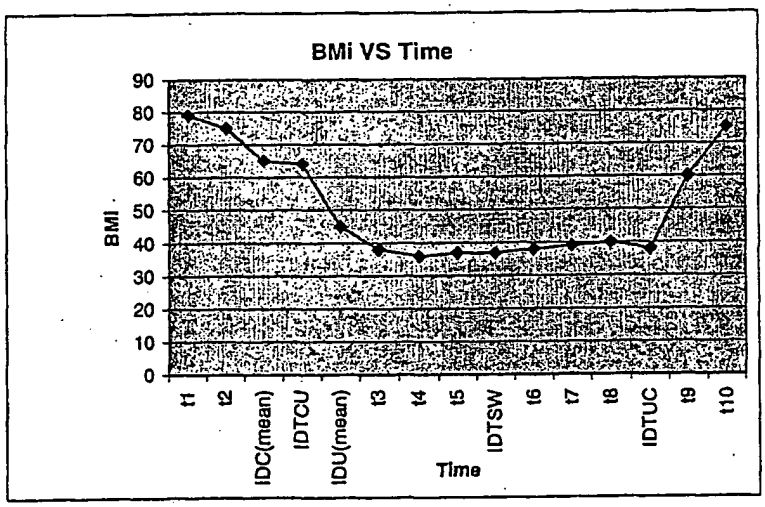

BMi VS Time
BMI
90
80
70
60
50
40
30
20
10
0
t1
t2
IDC(mean)
IDTCU
IDU(mean)
t3
t4
t5
IDTSW
t6
t7
t8
IDTUC
t9
t10
Time

FIG 13

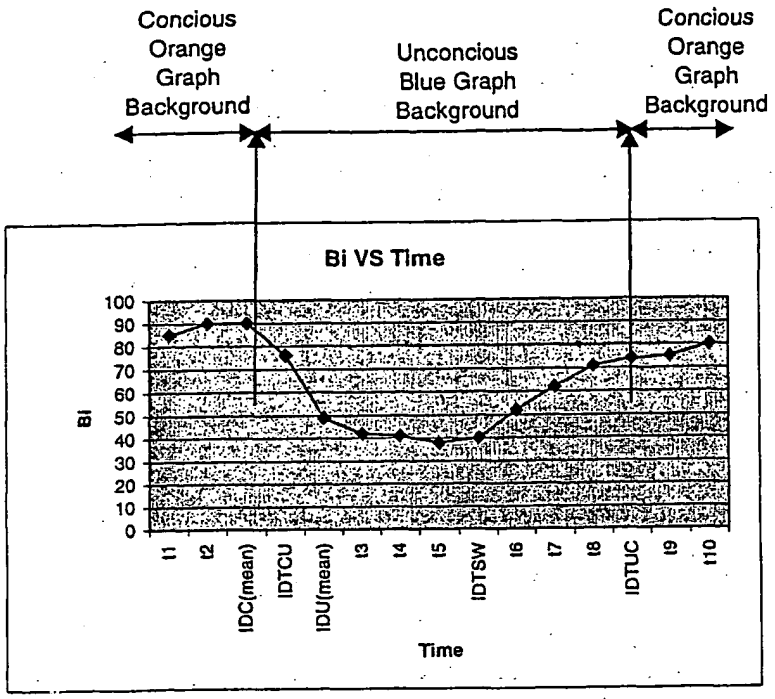

Concious
Orange
Graph
Background
Unconcious
Blue Graph
Background
Concious
Orange
Graph
Background
Bi VS Time
Bi
100
90
80
70
60
50
40
30
20
10
0
t1
t2
IDC(mean)
IDTCU
IDU(mean)
t3
t4
t5
IDTSW
t6
t7
t8
IDTUC
t9
t10
Time

FIG 14

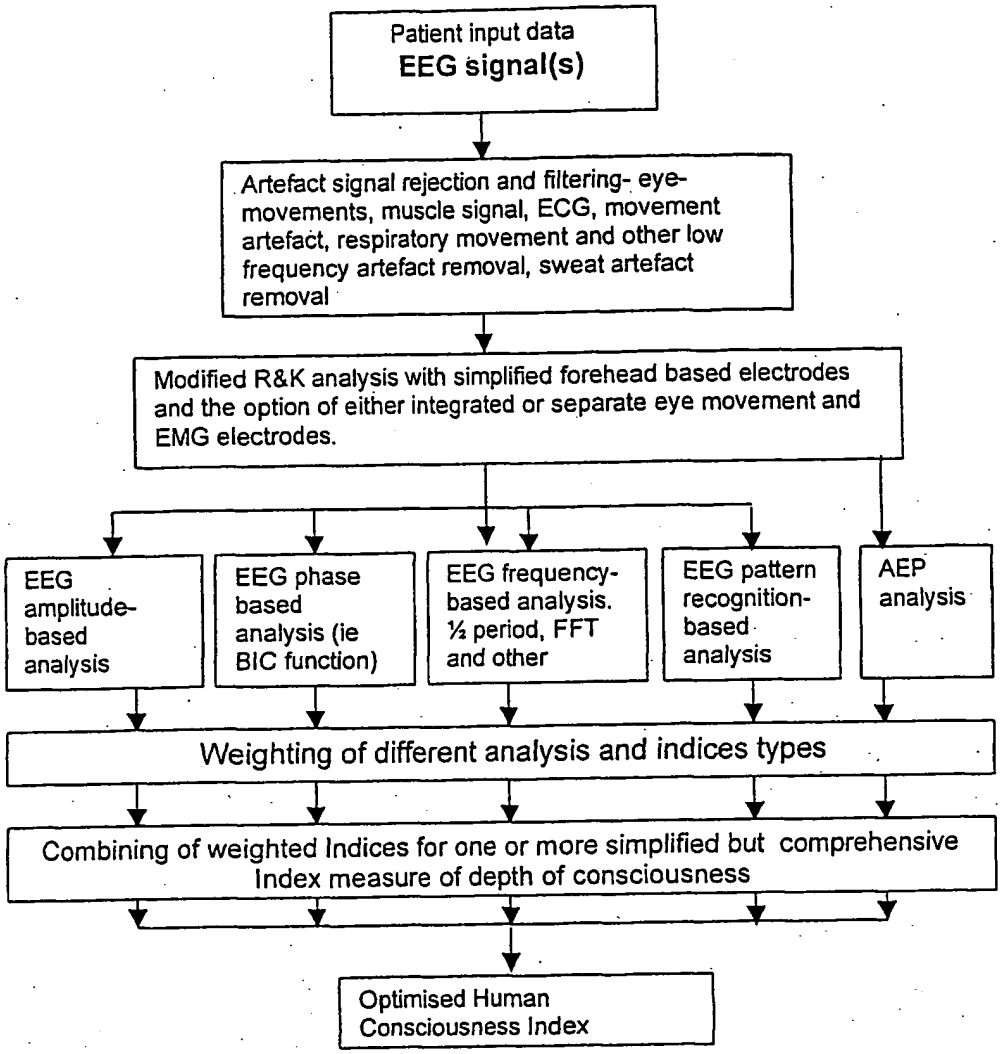

Patient input data
EEG signal(s)
Artefact signal rejection and filtering- eye-movements, muscle signal, ECG, movement artefact, respiratory movement and other low frequency artefact removal, sweat artefact removal
Modified R&K analysis with simplified forehead based electrodes and the option of either integrated or separate eye movement and EMG electrodes.
EEG amplitude-based analysis
EEG phase based analysis (ie BIC function)
EEG frequency-based analysis. ½ period, FFT and other
EEG pattern recognition-based analysis
AEP analysis
Weighting of different analysis and indices types
Combining of weighted Indices for one or more simplified but comprehensive Index measure of depth of consciousness
Optimised Human Consciousness Index

FIG 15

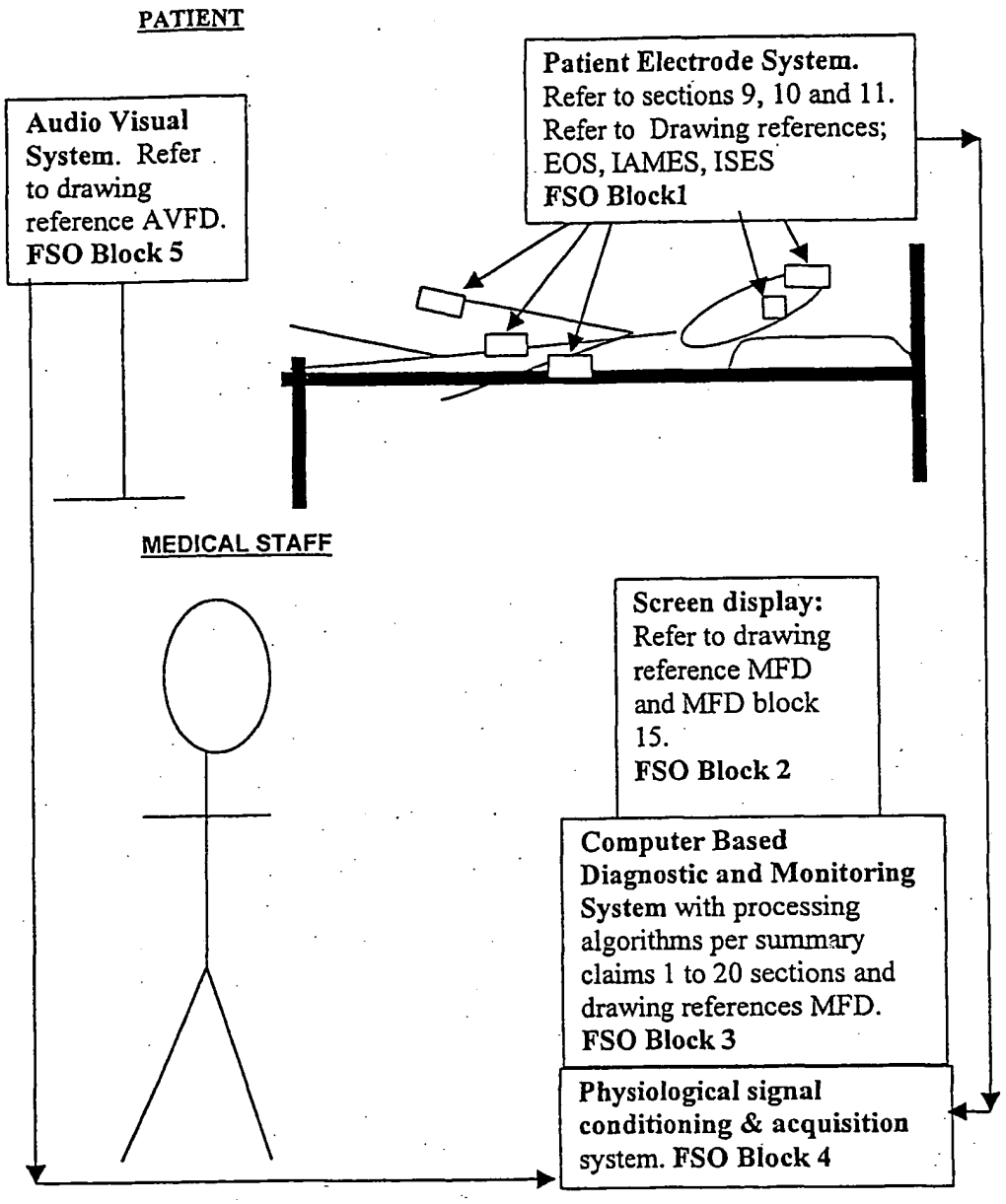

PATIENT
Patient Electrode System. Refer to sections 9, 10 and 11. Refer to Drawing references; EOS, IAMES, ISES FSO Block1
Audio Visual System. Refer to drawing reference AVFD. FSO Block 5
MEDICAL STAFF
Screen display: Refer to drawing reference MFD and MFD block 15. FSO Block 2
Computer Based Diagnostic and Monitoring System with processing algorithms per summary claims 1 to 20 sections and drawing references MFD. FSO Block 3
Physiological signal conditioning & acquisition system. FSO Block 4

FIG 16

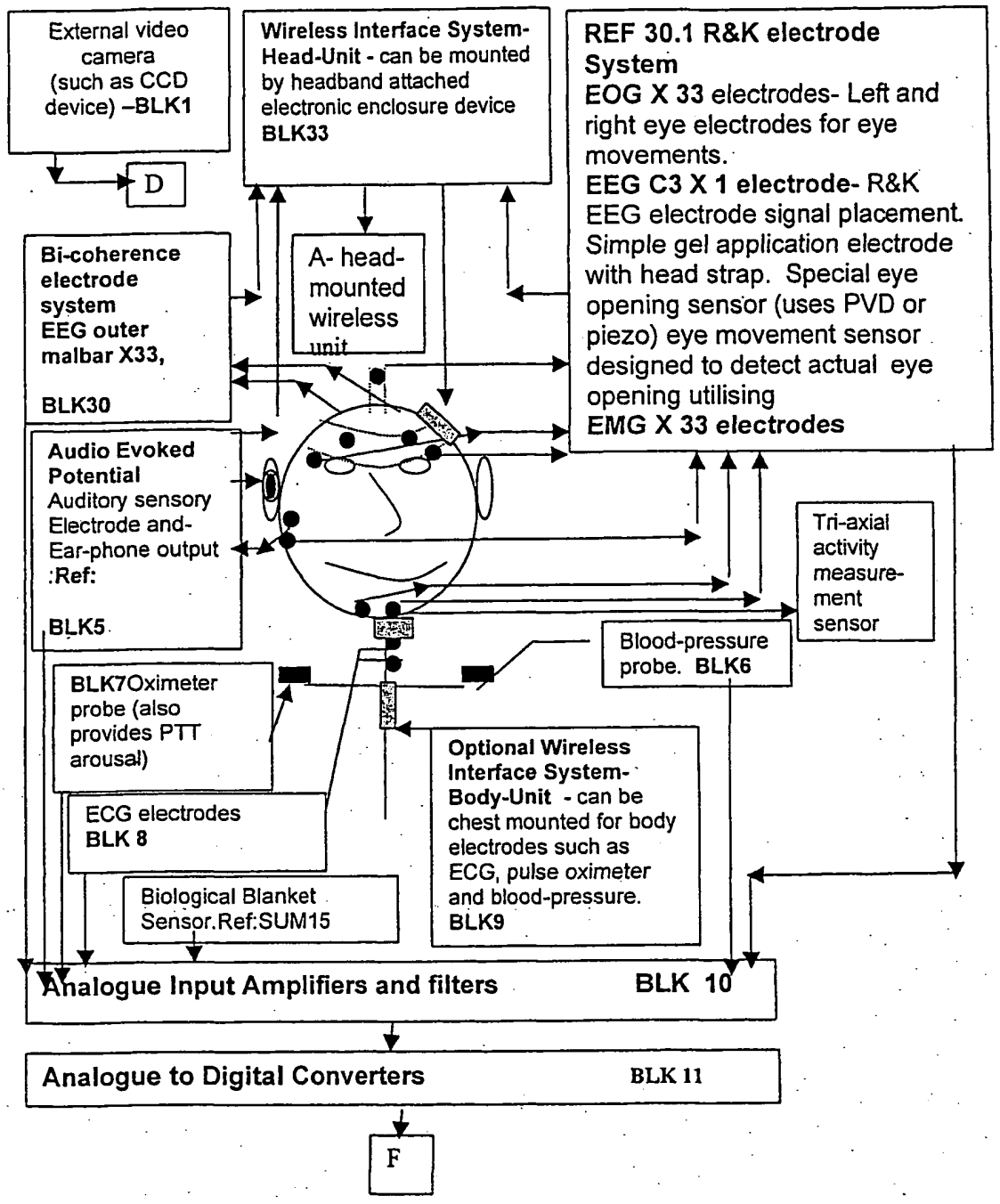

External video camera (such as CCD device) –BLK1
D
Wireless Interface System-Head-Unit - can be mounted by headband attached electronic enclosure device BLK33
REF 30.1 R&K electrode System
EOG X 33 electrodes- Left and right eye electrodes for eye movements.
EEG C3 X 1 electrode- R&K EEG electrode signal placement.
Simple gel application electrode with head strap. Special eye opening sensor (uses PVD or piezo) eye movement sensor designed to detect actual eye opening utilising
EMG X 33 electrodes
Bi-coherence electrode system EEG outer malbar X33,
BLK30
A- head-mounted wireless unit
Audio Evoked Potential Auditory sensory Electrode and-Ear-phone output :Ref:
BLK5
Tri-axial activity measure-ment sensor
Blood-pressure probe. BLK6
BLK7Oximeter probe (also provides PTT arousal)
ECG electrodes BLK 8
Optional Wireless Interface System-Body-Unit - can be chest mounted for body electrodes such as ECG, pulse oximeter and blood-pressure. BLK9
Biological Blanket Sensor.Ref:SUM15
Analogue Input Amplifiers and filters BLK 10
Analogue to Digital Converters BLK 11
F

FIG 17

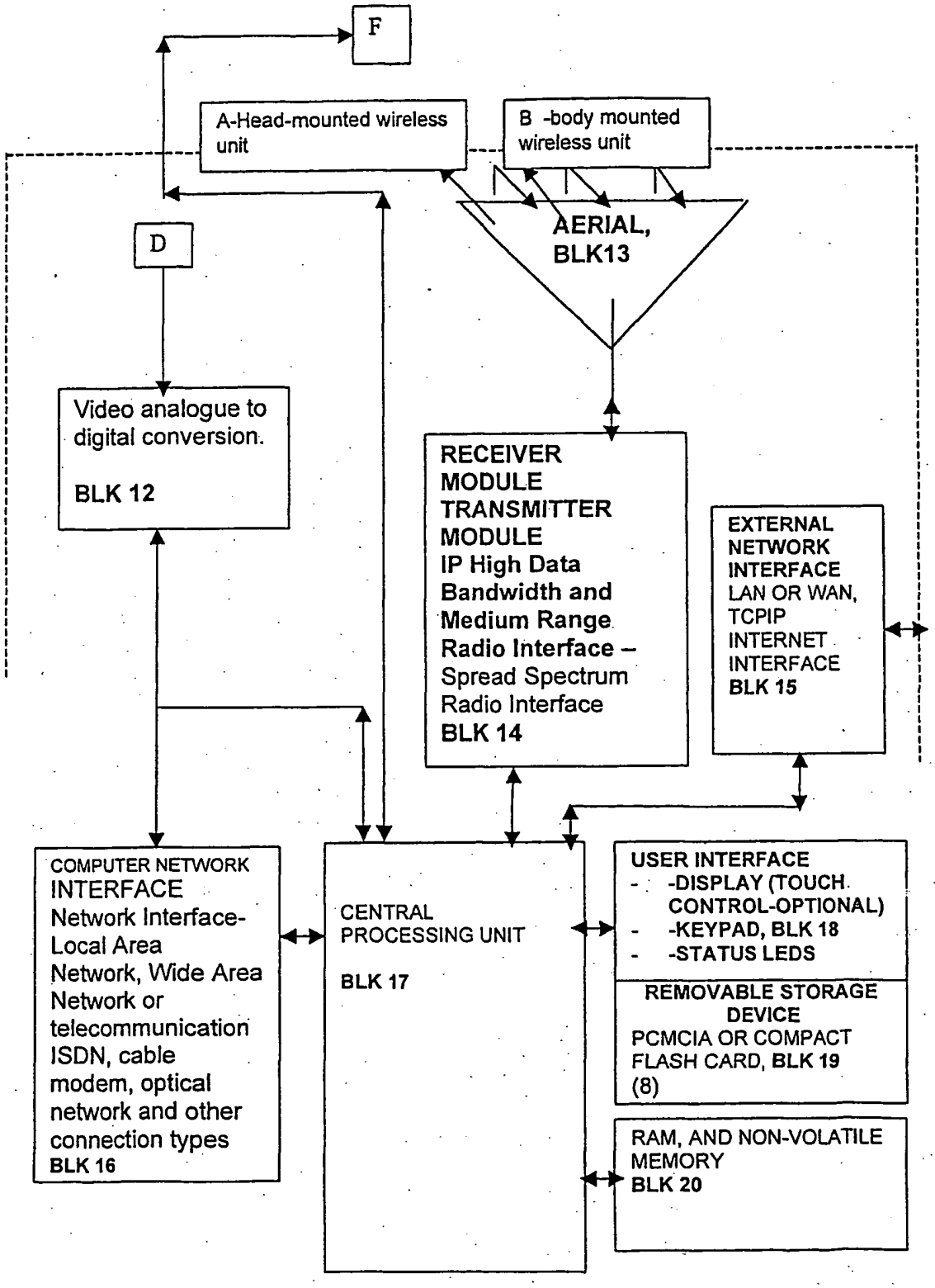

F
A-Head-mounted wireless unit
B -body mounted wireless unit
AERIAL, BLK13
D
Video analogue to digital conversion.
BLK 12
RECEIVER MODULE
TRANSMITTER MODULE
IP High Data Bandwidth and Medium Range Radio Interface – Spread Spectrum Radio Interface
BLK 14
EXTERNAL NETWORK INTERFACE
LAN OR WAN, TCPIP INTERNET INTERFACE
BLK 15
COMPUTER NETWORK INTERFACE
Network Interface-Local Area Network, Wide Area Network or telecommunication ISDN, cable modem, optical network and other connection types
BLK 16
CENTRAL PROCESSING UNIT
BLK 17
USER INTERFACE
- -DISPLAY (TOUCH CONTROL-OPTIONAL)
- -KEYPAD, BLK 18
- -STATUS LEDS
REMOVABLE STORAGE DEVICE
PCMCIA OR COMPACT FLASH CARD, BLK 19
(8)
RAM, AND NON-VOLATILE MEMORY
BLK 20

FIG 17 (cont)

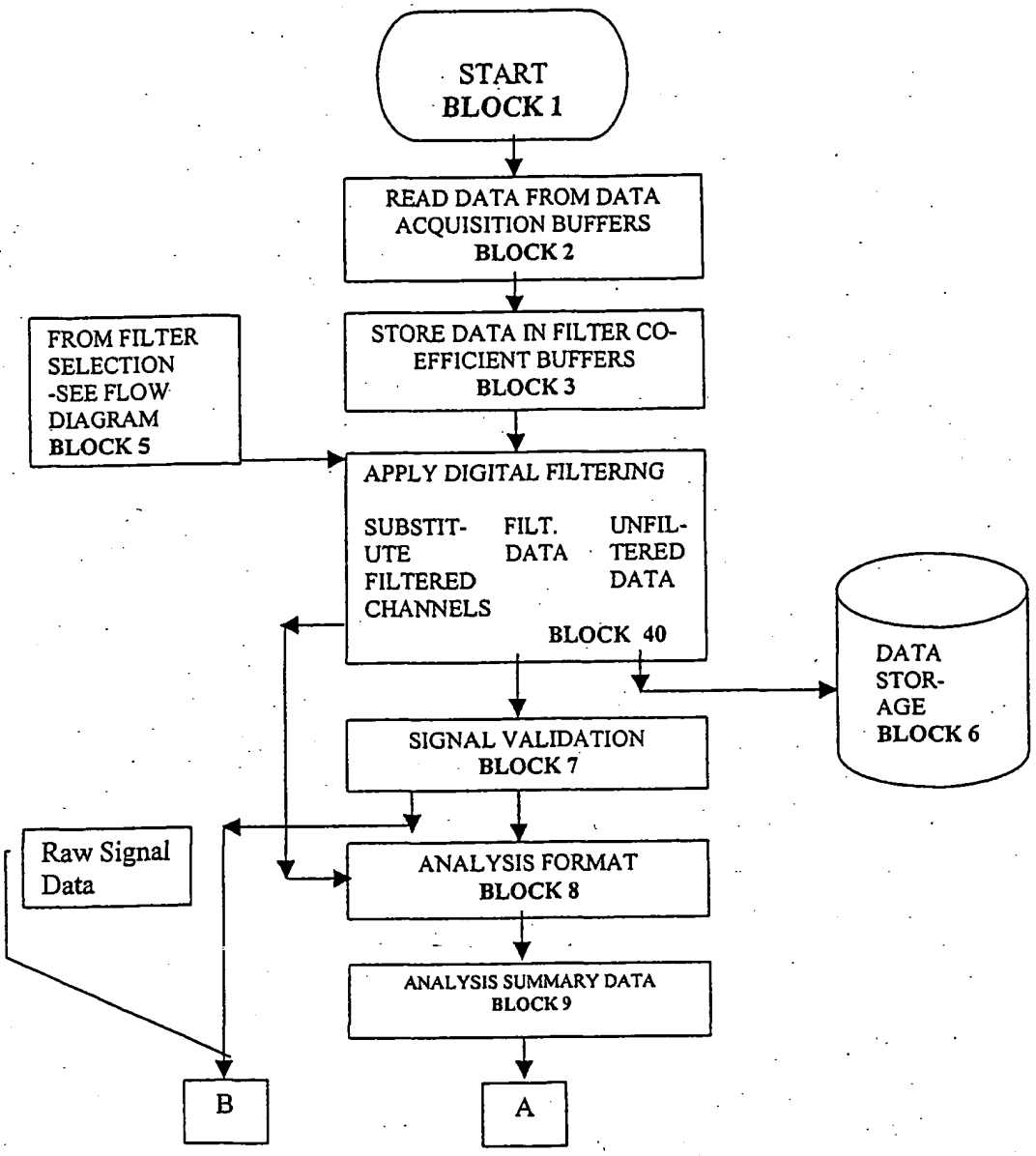

START
BLOCK 1
READ DATA FROM DATA ACQUISITION BUFFERS
BLOCK 2
STORE DATA IN FILTER CO-EFFICIENT BUFFERS
BLOCK 3
FROM FILTER SELECTION -SEE FLOW DIAGRAM
BLOCK 5
APPLY DIGITAL FILTERING
SUBSTIT-UTE FILTERED CHANNELS
FILT. DATA
UNFIL-TERED DATA
BLOCK 40
DATA STOR-AGE
BLOCK 6
SIGNAL VALIDATION
BLOCK 7
Raw Signal Data
ANALYSIS FORMAT
BLOCK 8
ANALYSIS SUMMARY DATA
BLOCK 9
B
A

FIG 18

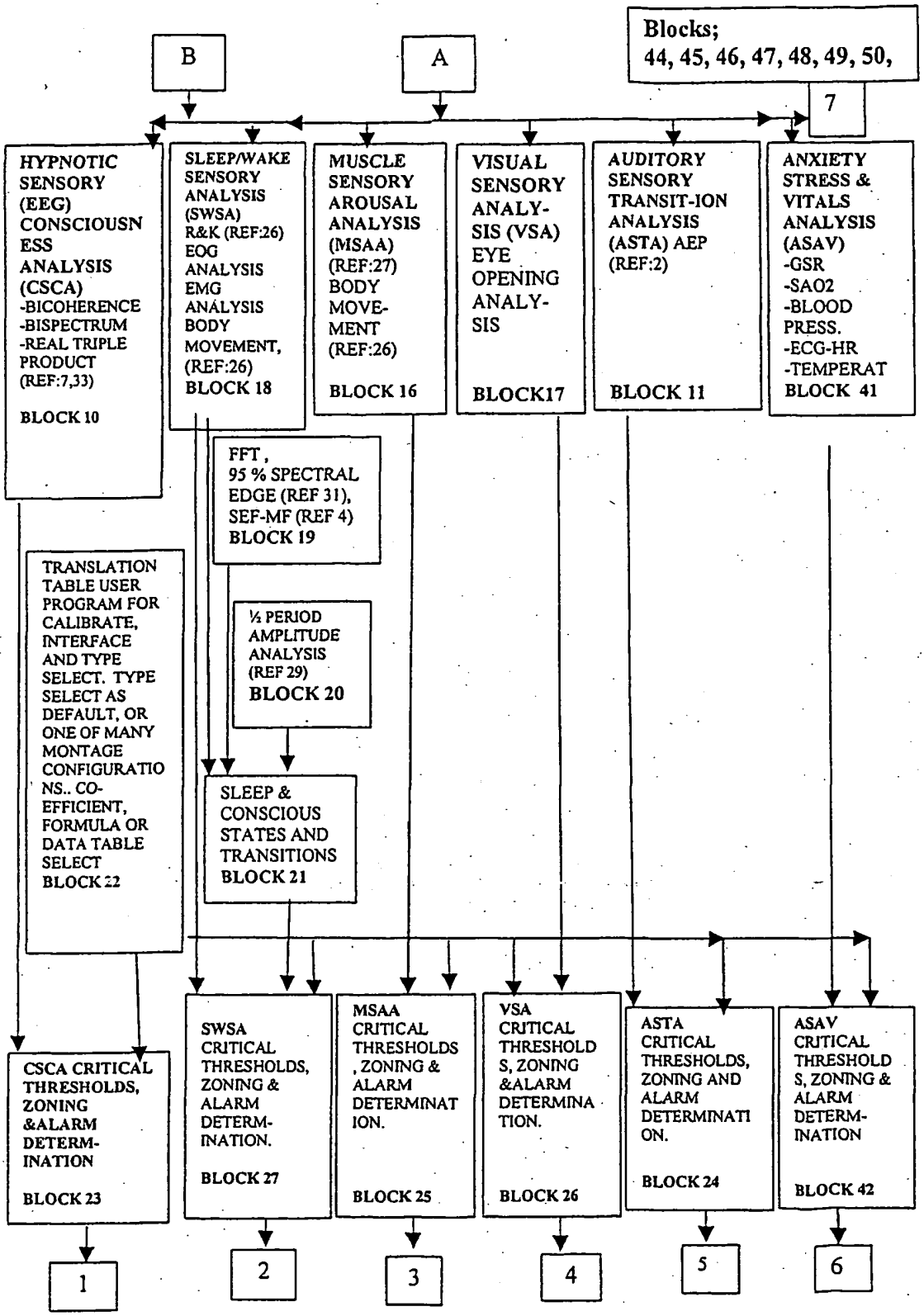

B
A
Blocks;
44, 45, 46, 47, 48, 49, 50,
7
HYPNOTIC SENSORY (EEG) CONSCIOUSNESS ANALYSIS (CSCA) -BICOHERENCE -BISPECTRUM -REAL TRIPLE PRODUCT (REF:7,33)
BLOCK 10
SLEEP/WAKE SENSORY ANALYSIS (SWSA) R&K (REF:26) EOG ANALYSIS EMG ANALYSIS BODY MOVEMENT, (REF:26)
BLOCK 18
MUSCLE SENSORY AROUSAL ANALYSIS (MSAA) (REF:27) BODY MOVE-MENT (REF:26)
BLOCK 16
VISUAL SENSORY ANALY-SIS (VSA) EYE OPENING ANALY-SIS
BLOCK17
AUDITORY SENSORY TRANSIT-ION ANALYSIS (ASTA) AEP (REF:2)
BLOCK 11
ANXIETY STRESS & VITALS ANALYSIS (ASAV) -GSR -SAO2 -BLOOD PRESS. -ECG-HR -TEMPERAT
BLOCK 41
FFT, 95 % SPECTRAL EDGE (REF 31), SEF-MF (REF 4)
BLOCK 19
TRANSLATION TABLE USER PROGRAM FOR CALIBRATE, INTERFACE AND TYPE SELECT. TYPE SELECT AS DEFAULT, OR ONE OF MANY MONTAGE CONFIGURATIONS.. CO-EFFICIENT, FORMULA OR DATA TABLE SELECT
BLOCK 22
½ PERIOD AMPLITUDE ANALYSIS (REF 29)
BLOCK 20
SLEEP & CONSCIOUS STATES AND TRANSITIONS
BLOCK 21
CSCA CRITICAL THRESHOLDS, ZONING &ALARM DETERM-INATION
BLOCK 23
SWSA CRITICAL THRESHOLDS, ZONING & ALARM DETERM-INATION.
BLOCK 27
MSAA CRITICAL THRESHOLDS, ZONING & ALARM DETERMINAT ION.
BLOCK 25
VSA CRITICAL THRESHOLD S, ZONING &ALARM DETERMINA TION.
BLOCK 26
ASTA CRITICAL THRESHOLDS, ZONING AND ALARM DETERMINATI ON.
BLOCK 24
ASAV CRITICAL THRESHOLD S, ZONING & ALARM DETERM-INATION
BLOCK 42
1
2
3
4
5
6

FIG 18 (cont)(i)

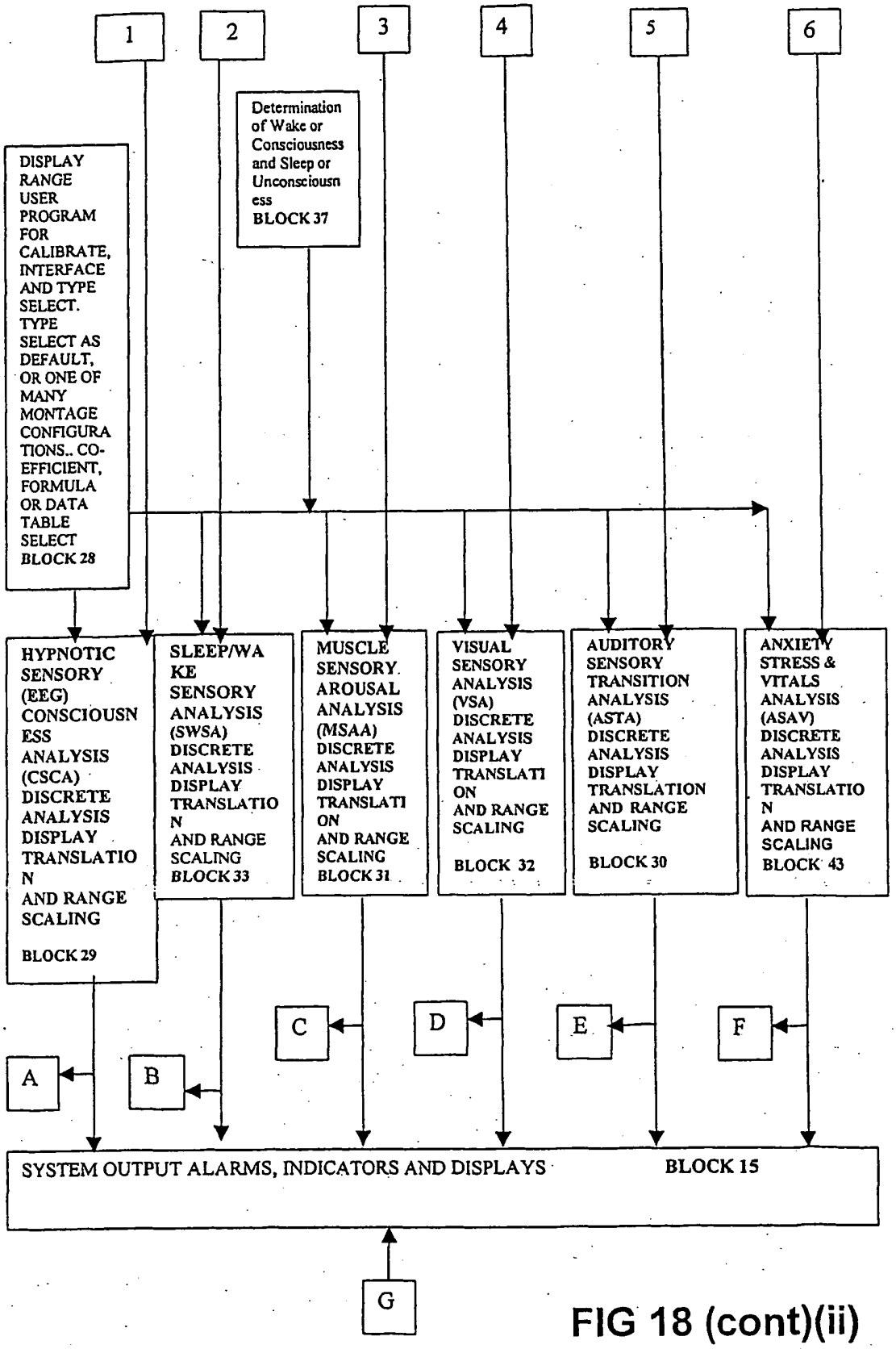


FIG 18 (cont)(ii)

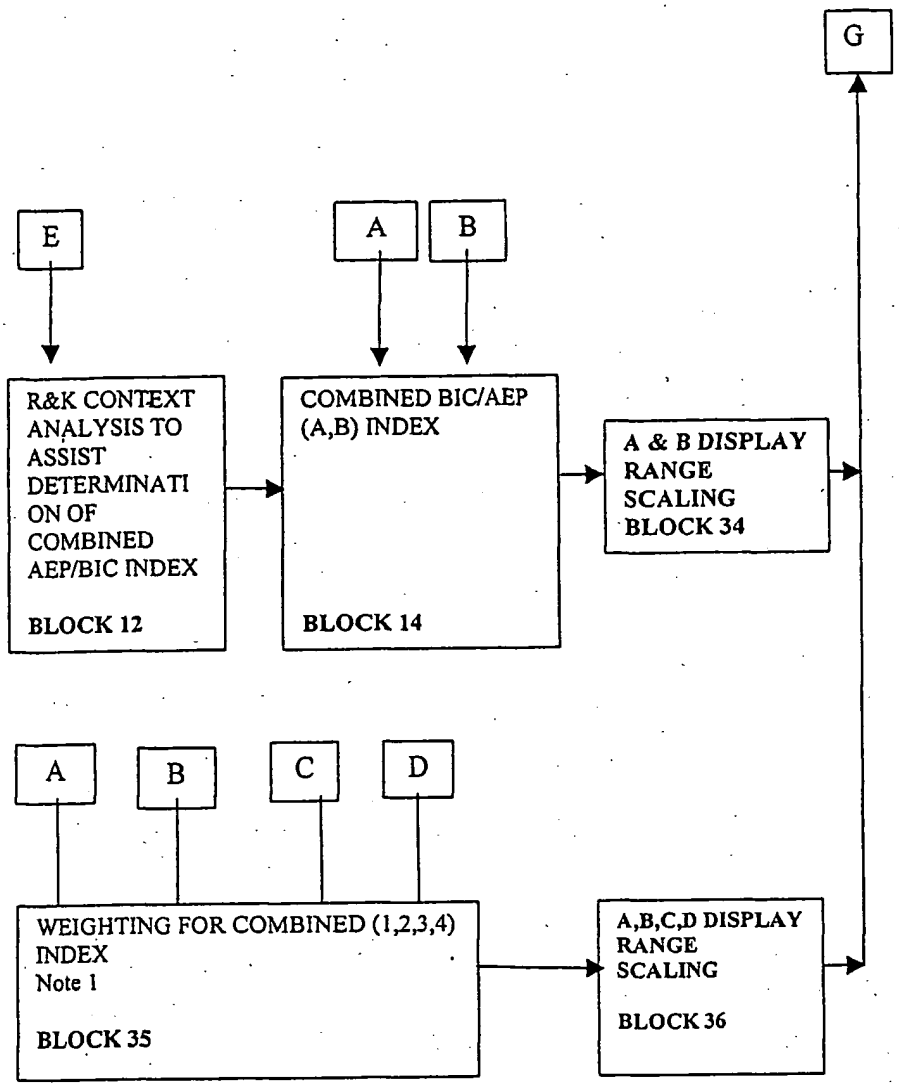


FIG 18 (cont)(iii)

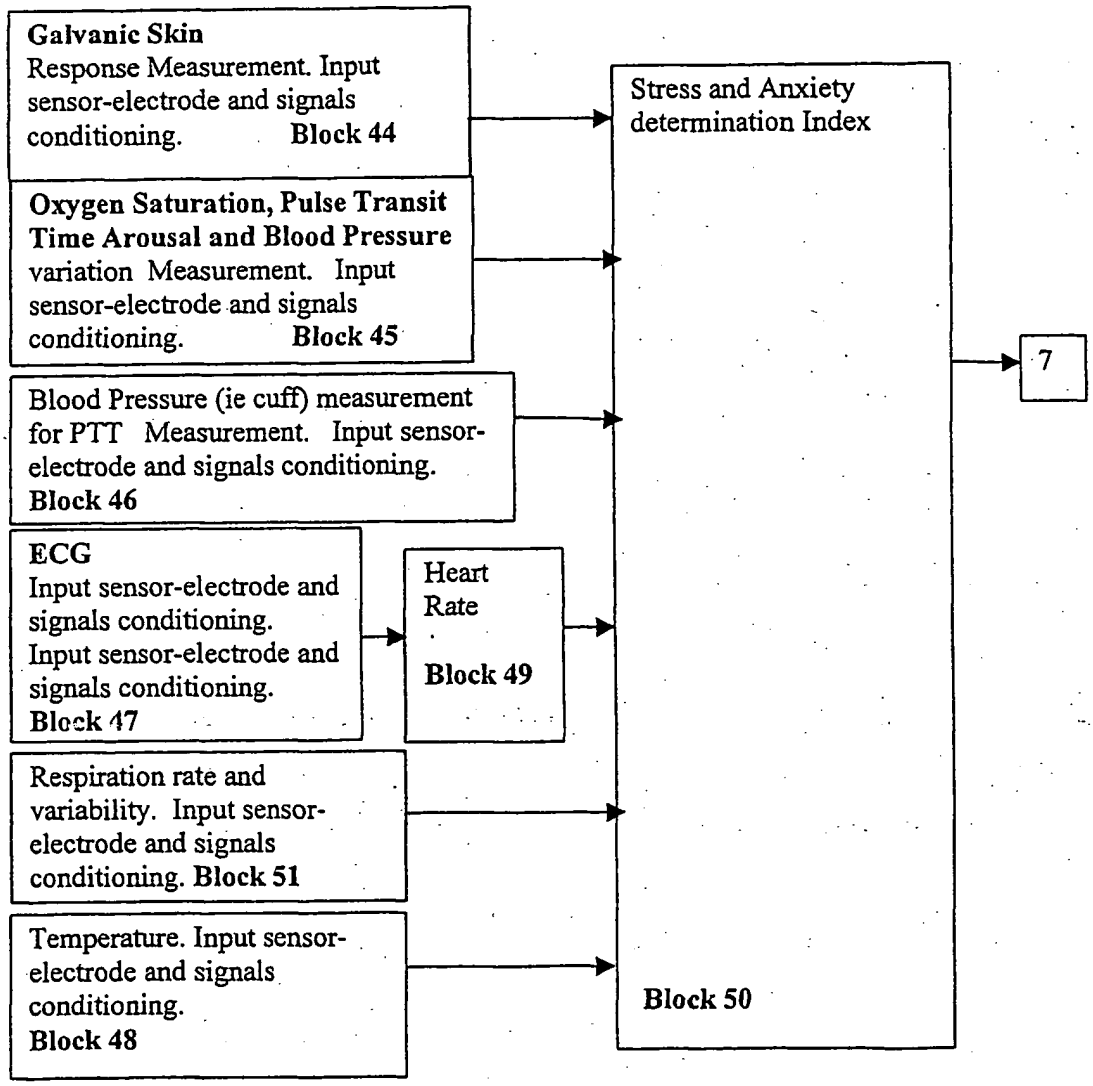


FIG 18 (cont)(iv)

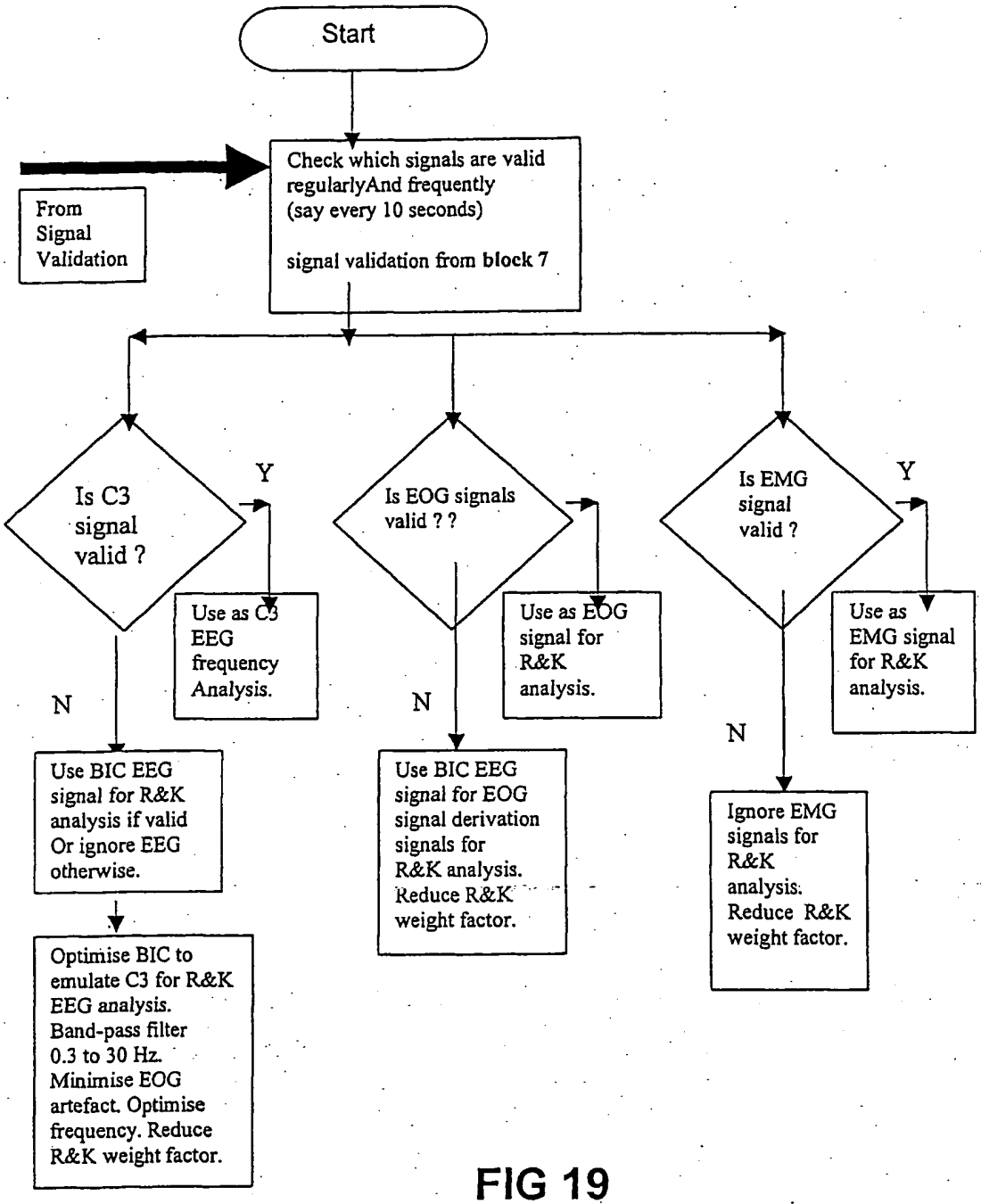

Start
From Signal Validation
Check which signals are valid regularlyAnd frequently (say every 10 seconds)
signal validation from block 7
Is C3 signal valid ?
Y
Use as C3 EEG frequency Analysis.
N
Use BIC EEG signal for R&K analysis if valid Or ignore EEG otherwise.
Optimise BIC to emulate C3 for R&K EEG analysis. Band-pass filter 0.3 to 30 Hz. Minimise EOG artefact. Optimise frequency. Reduce R&K weight factor.
Is EOG signals valid ? ?
Y
Use as EOG signal for R&K analysis.
N
Use BIC EEG signal for EOG signal derivation signals for R&K analysis. Reduce R&K weight factor.
Is EMG signal valid ?
Y
Use as EMG signal for R&K analysis.
N
Ignore EMG signals for R&K analysis. Reduce R&K weight factor.

FIG 19

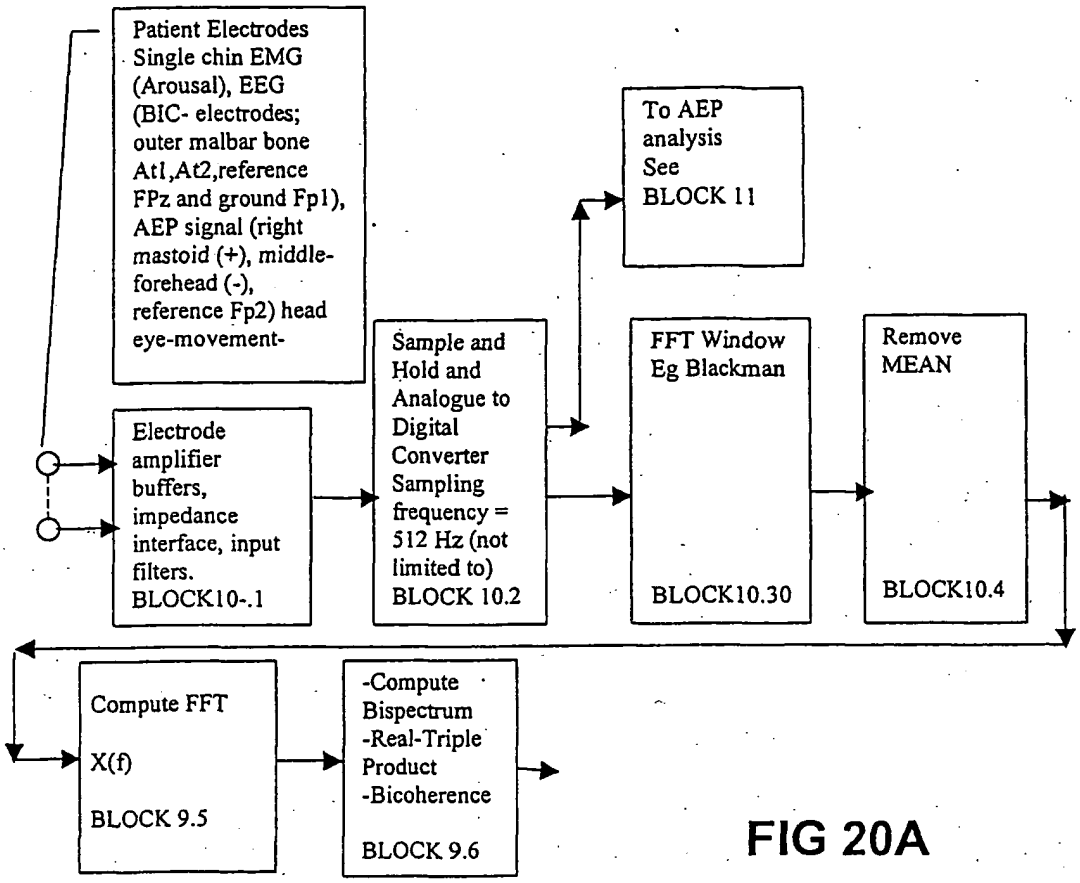


FIG 20A

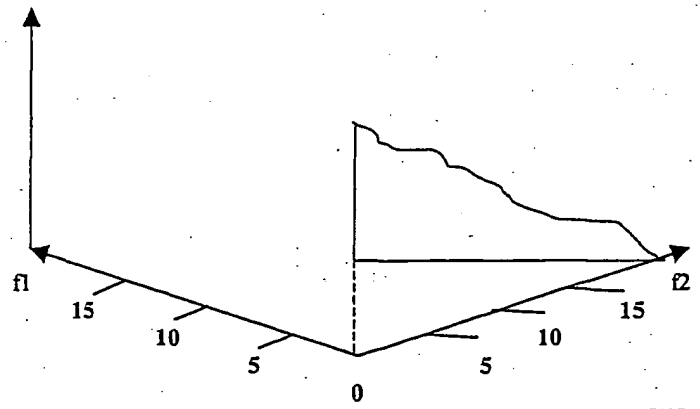


FIG 20B

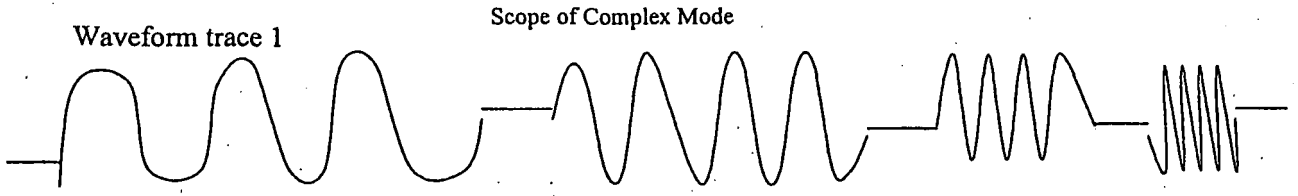


FIG 21A

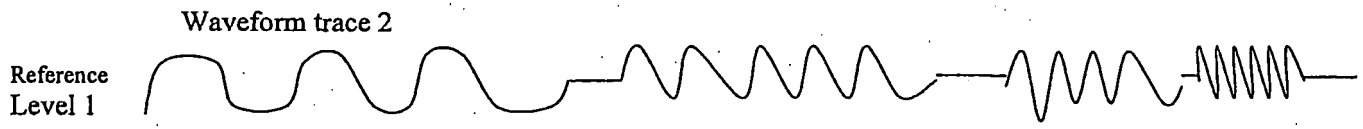


FIG 21B

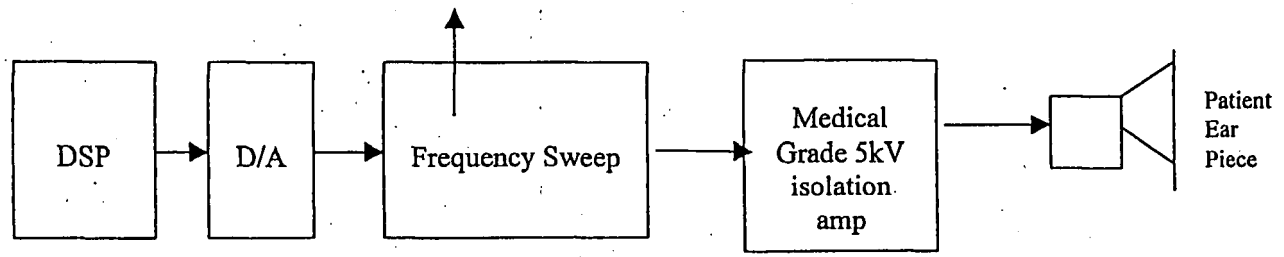


FIG 21C

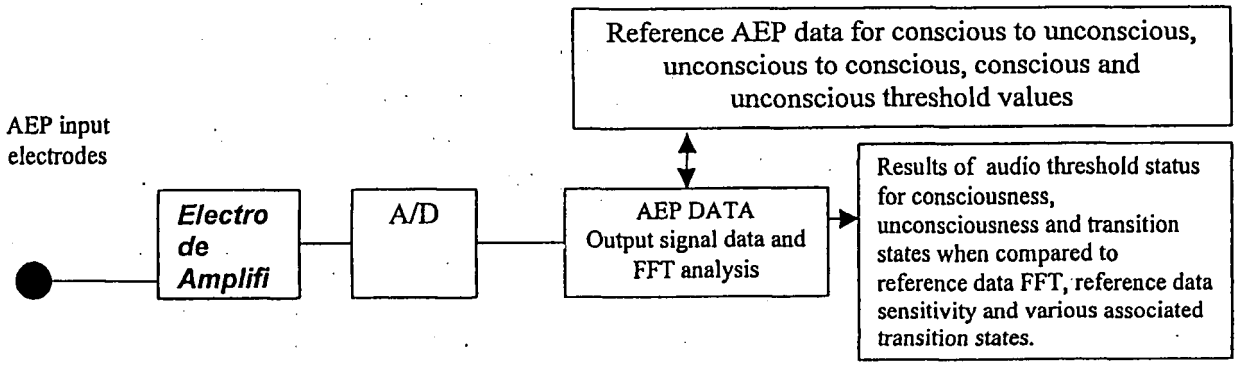


FIG 21D

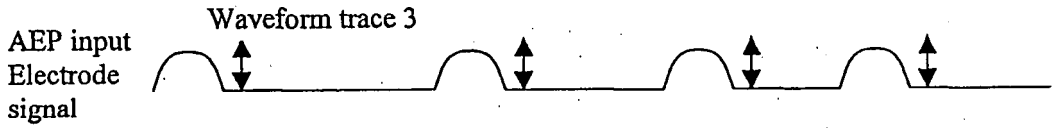


FIG 21E

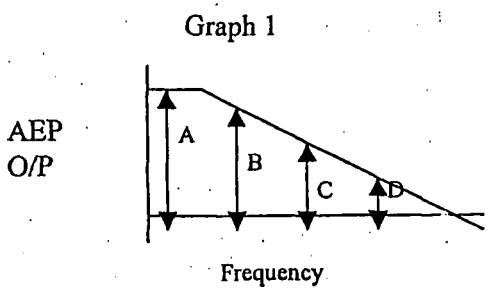


FIG 21F

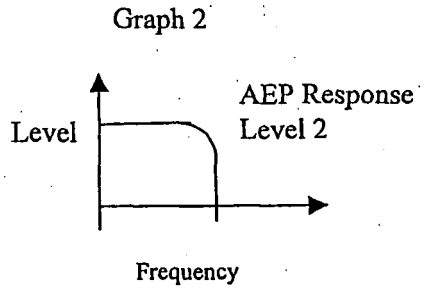


FIG 21G

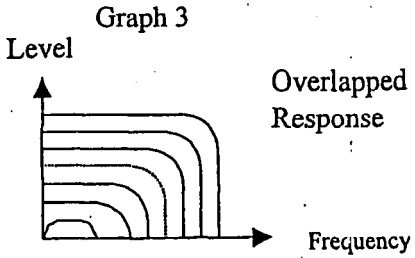


FIG 21H

Context Analysis Method

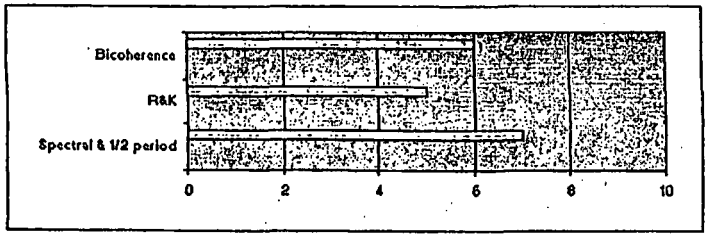


FIG 22A

Context Analysis Probability

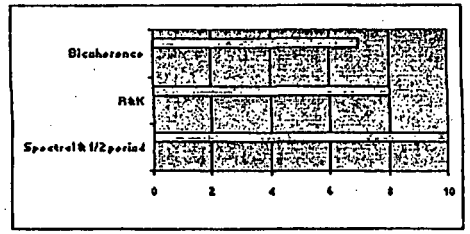


FIG 22B

Validate

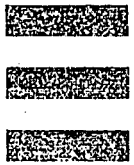


FIG 22a

Validate

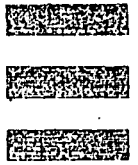


FIG 22b

Transition Analysis Method

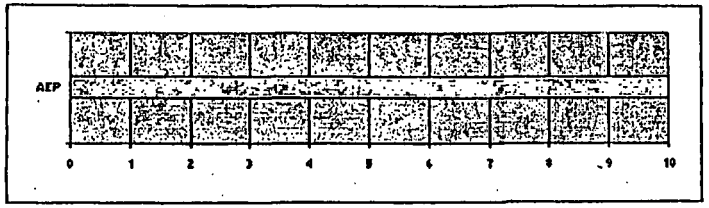


FIG 22C

Transition Analysis Probability

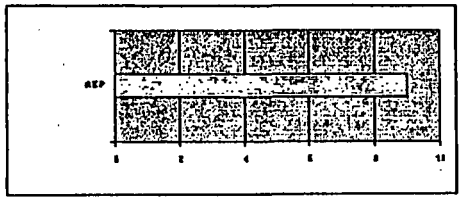


FIG 22D

FIG 22c

FIG 22d

Movement Analysis Method

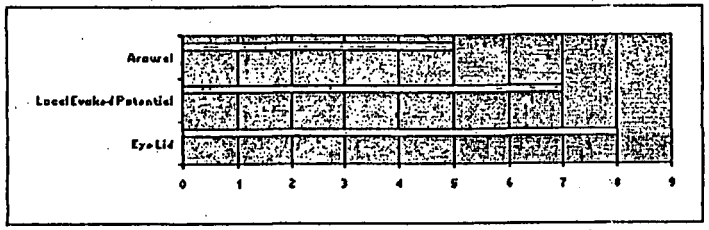


FIG 22E

Movement Analysis Probability

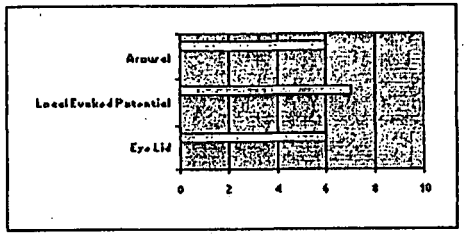


FIG 22F

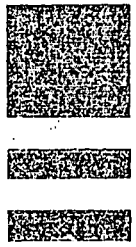


FIG 22e

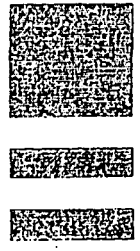
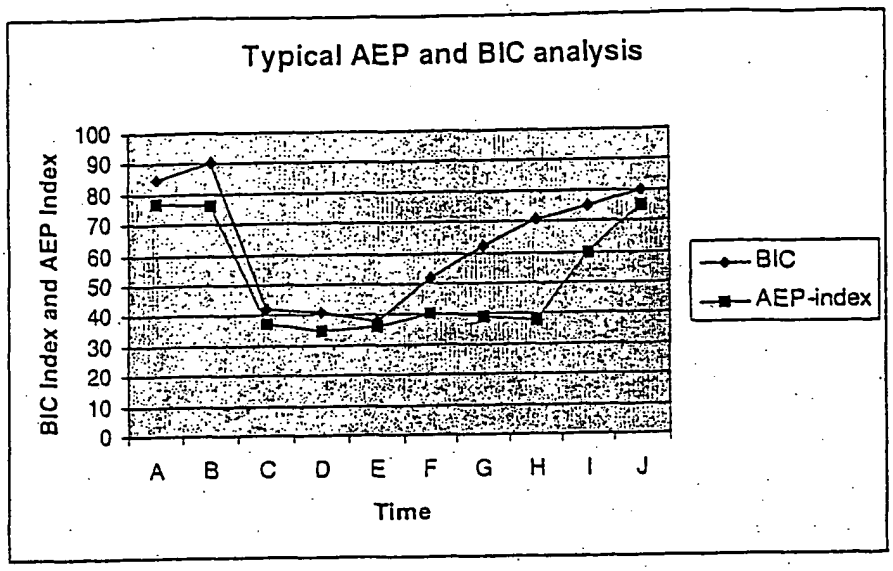
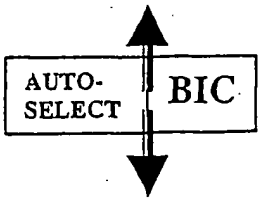
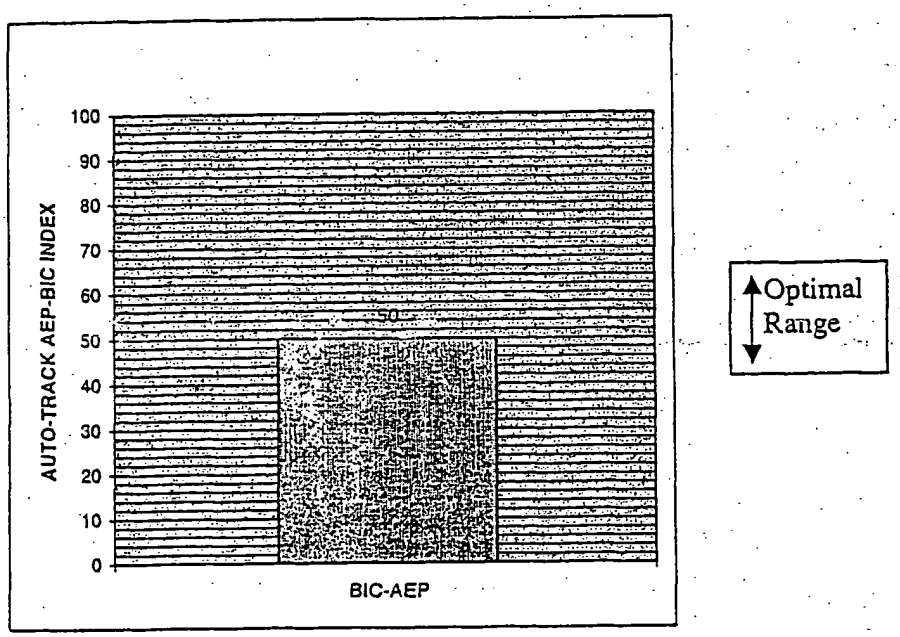


FIG 22f



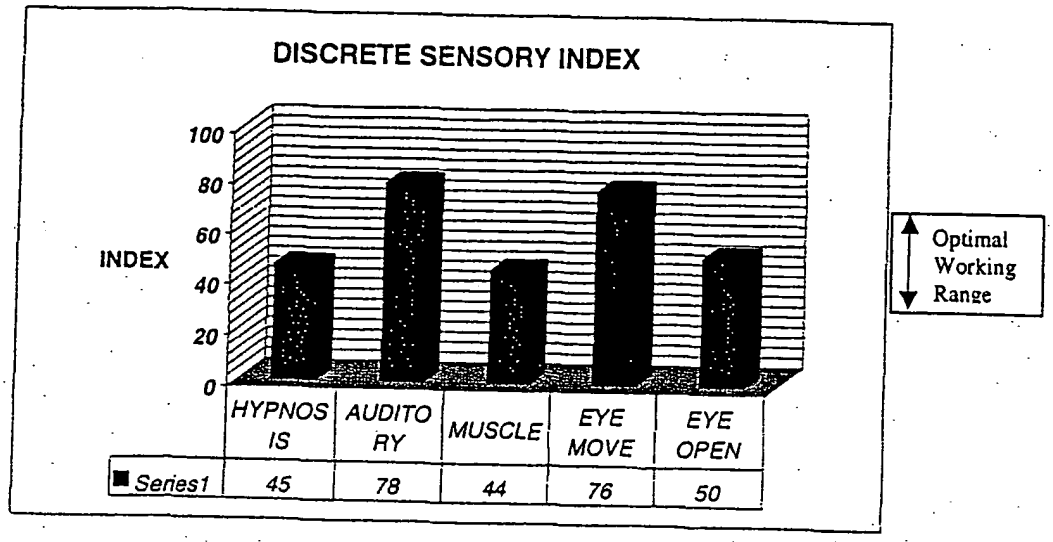




VALUE

HIGH-RED
OPTIMAL-GREEN
LOW-ORANGE

FIG 23A



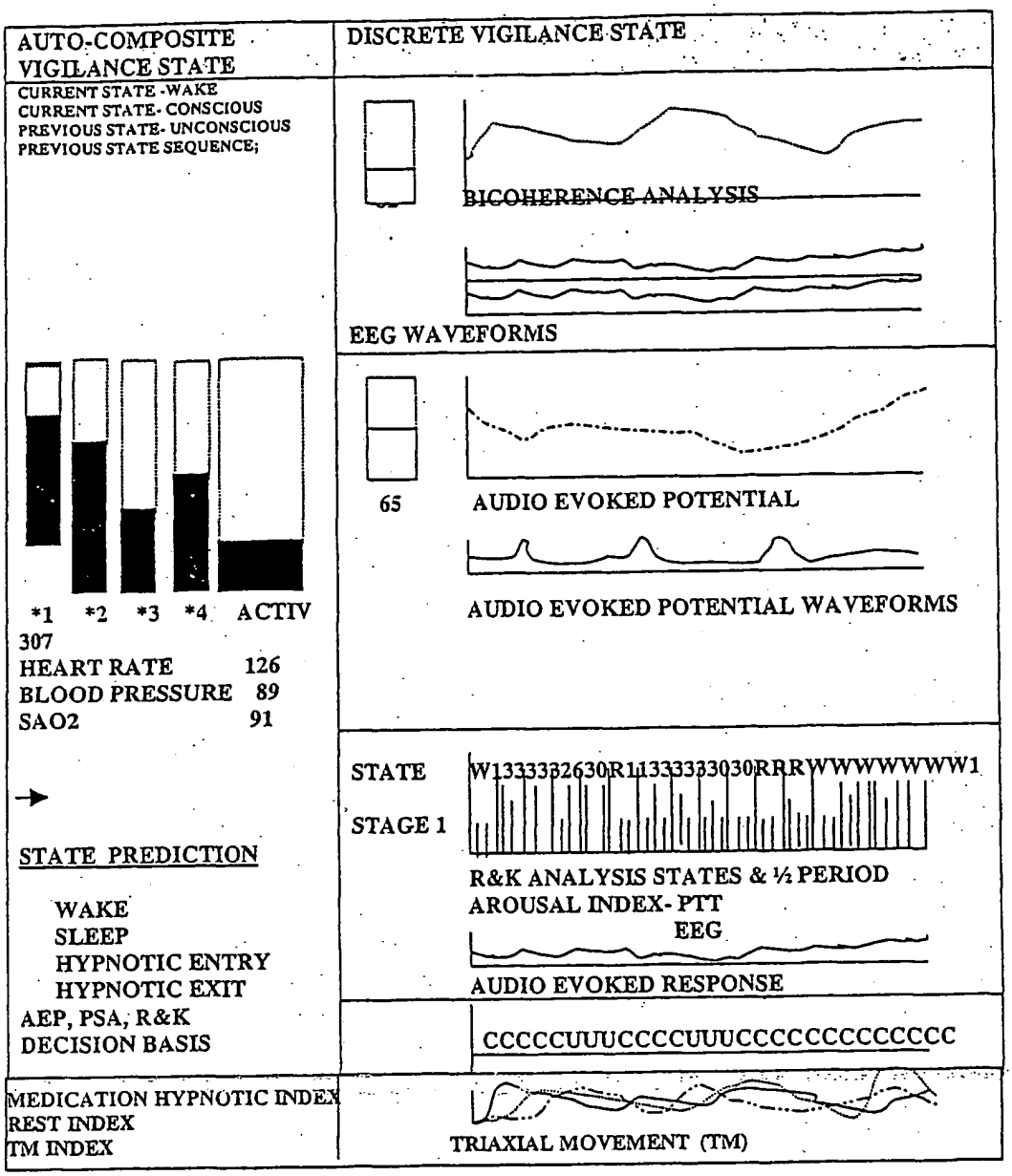
SIGNAL VALIDATION

VERY POOR-RED
OPTIMAL-GREEN
POOR-ORANGE

CURRENTCONSCIOUS STATE- CONSCIOUS
TRANSITION STATUS- CONSCIOUS TO UNCONSCIOUS

SIGNAL VALIDATION HINT : CHECK BIC + ELECTRODE
ANALYSIS VALIDATION HINT : BIC ANALYSIS LOW QUALITY

FIG 23B



KEY;
1 = STAGE 1
2 = STAGE 2
3 = STAGE 3
4 = STAGE 4, R = REM
W = WAKE
C = CONSCIOUS, U= UNCONSCOIOUS

FIG 23C

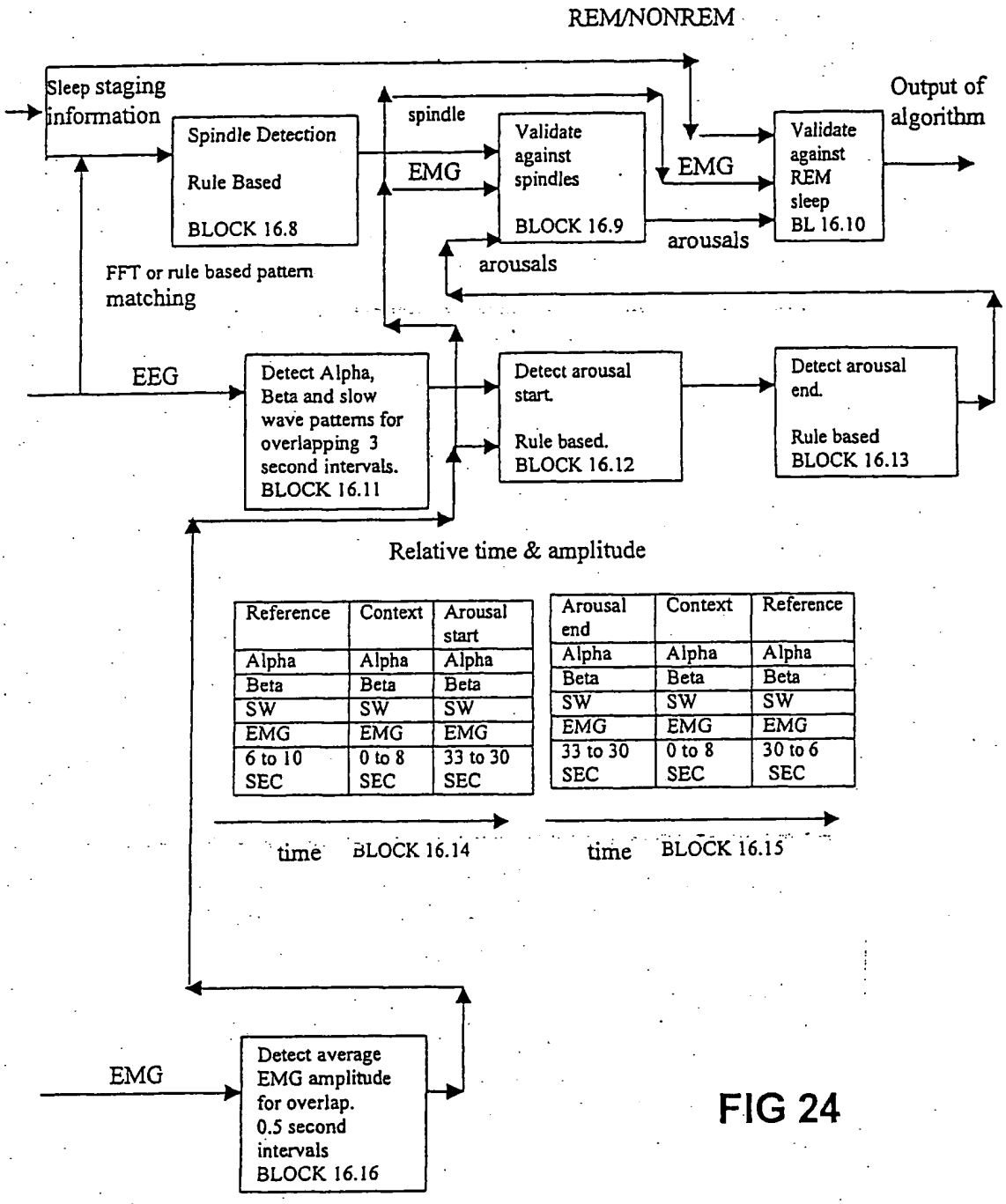
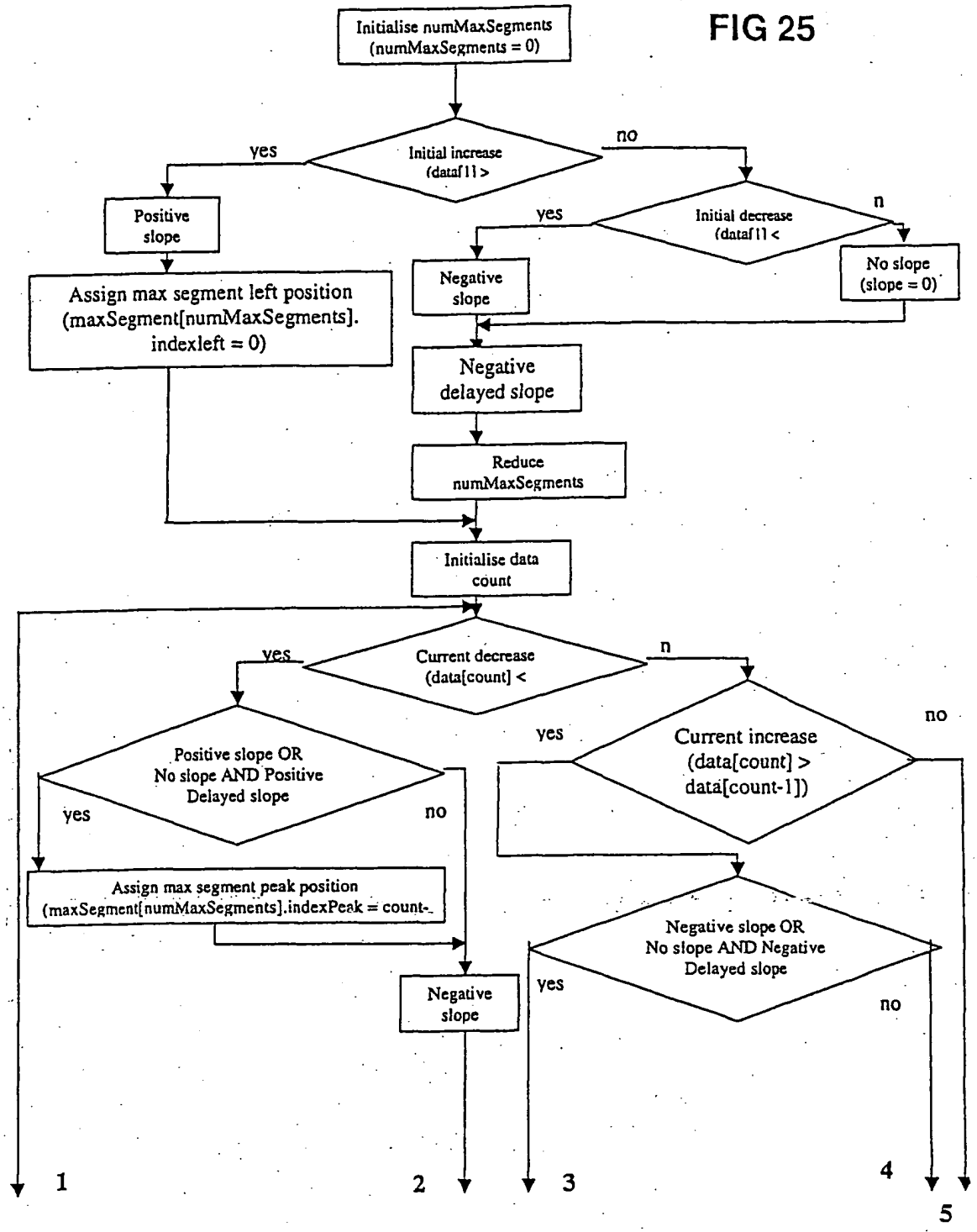

REM/NONREM
Sleep staging information
Spindle Detection
Rule Based
BLOCK 16.8
spindle
EMG
Validate against spindles
BLOCK 16.9
EMG
Validate against REM sleep
BL 16.10
Output of algorithm
arousals
arousals
FFT or rule based pattern matching
EEG
Detect Alpha, Beta and slow wave patterns for overlapping 3 second intervals.
BLOCK 16.11
Detect arousal start.
Rule based.
BLOCK 16.12
Detect arousal end.
Rule based
BLOCK 16.13
Relative time & amplitude
Reference | Context | Arousal start
Alpha | Alpha | Alpha
Beta | Beta | Beta
SW | SW | SW
EMG | EMG | EMG
6 to 10 SEC | 0 to 8 SEC | 33 to 30 SEC
time
BLOCK 16.14
Arousal end | Context | Reference
Alpha | Alpha | Alpha
Beta | Beta | Beta
SW | SW | SW
EMG | EMG | EMG
33 to 30 SEC | 0 to 8 SEC | 30 to 6 SEC
time
BLOCK 16.15
EMG
Detect average EMG amplitude for overlap.
0.5 second intervals
BLOCK 16.16

FIG 24

FIG 25


Initialise numMaxSegments
(numMaxSegments = 0)
Initial increase
(dataf11 >
yes
no
Positive
slope
Initial decrease
(dataf11 <
yes
n
Negative
slope
No slope
(slope = 0)
Assign max segment left position
(maxSegment[numMaxSegments].
indexleft = 0)
Negative
delayed slope
Reduce
numMaxSegments
Initialise data
count
Current decrease
(data[count] <
yes
n
Positive slope OR
No slope AND Positive
Delayed slope
yes
no
Current increase
(data[count] >
data[count-1])
yes
no
Assign max segment peak position
(maxSegment[numMaxSegments].indexPeak = count-
Negative slope OR
No slope AND Negative
Delayed slope
Negative
slope
yes
no
1
2
3
4
5

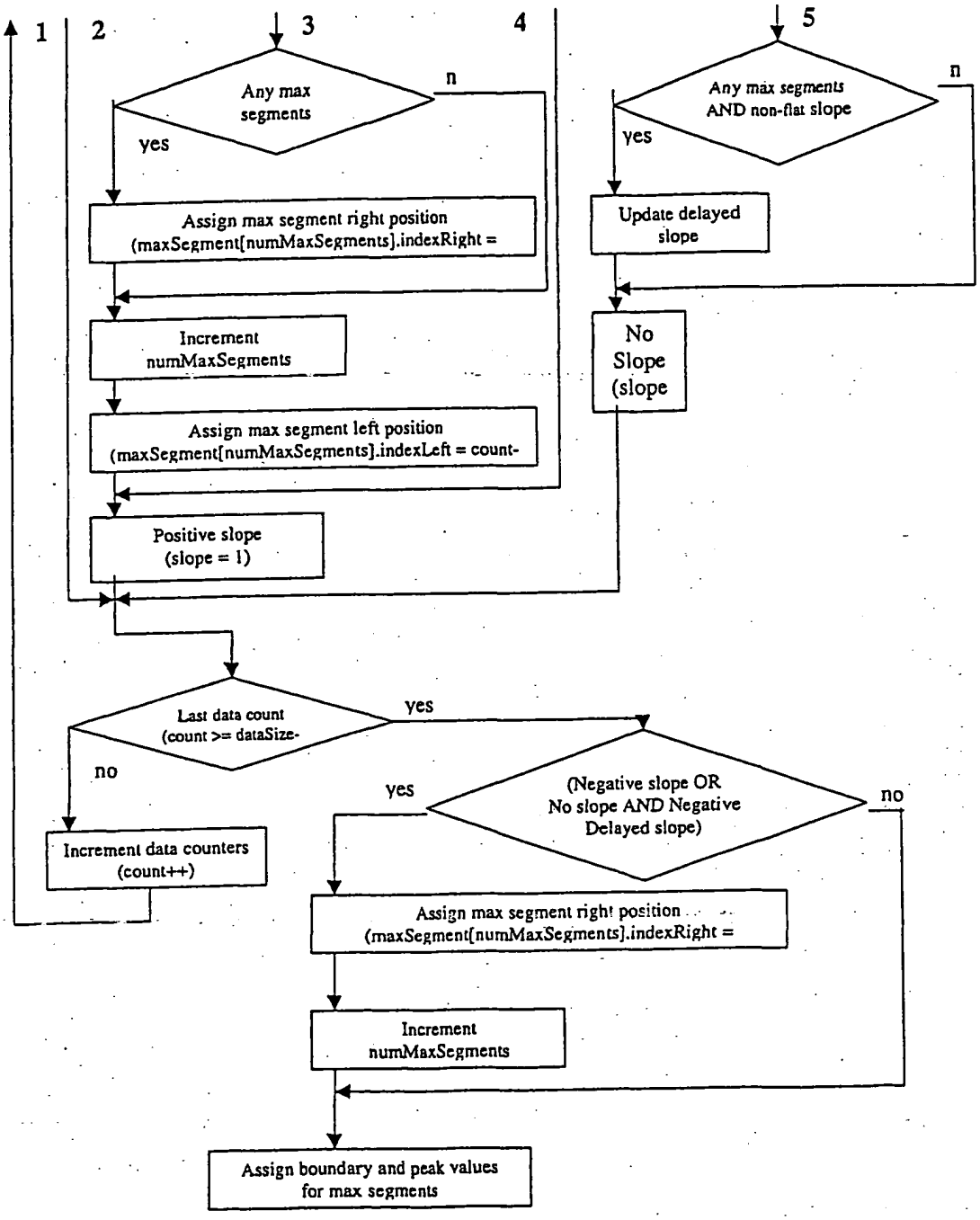
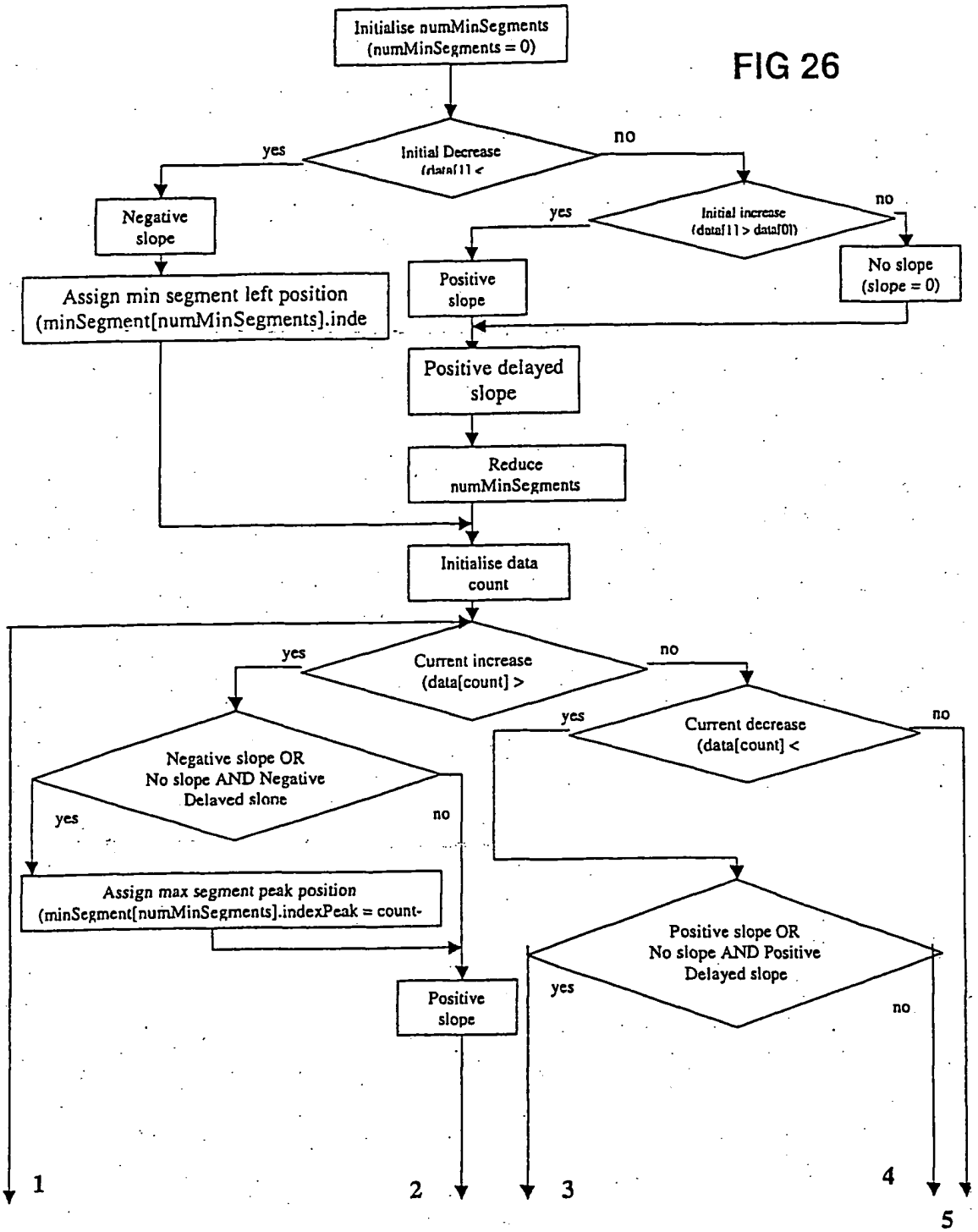

1
2
3
4
5
Any max segments
n
yes
Assign max segment right position (maxSegment[numMaxSegments].indexRight =
Increment numMaxSegments
Assign max segment left position (maxSegment[numMaxSegments].indexLeft = count-
Positive slope (slope = 1)
Any max segments AND non-flat slope
n
yes
Update delayed slope
No Slope (slope
Last data count (count >= dataSize-
yes
no
Increment data counters (count++)
yes
(Negative slope OR No slope AND Negative Delayed slope)
no
Assign max segment right position (maxSegment[numMaxSegments].indexRight =
Increment numMaxSegments
Assign boundary and peak values for max segments

FIG 25 (cont)

FIG 26


Initialise numMinSegments
(numMinSegments = 0)
Initial Decrease
(dataf1] <
yes
no
Negative
slope
Initial increase
(dataf1] > dataf0])
yes
no
Positive
slope
No slope
(slope = 0)
Assign min segment left position
(minSegment[numMinSegments].inde
Positive delayed
slope
Reduce
numMinSegments
Initialise data
count
Current increase
(data[count] >
yes
no
Negative slope OR
No slope AND Negative
Delayed slope
yes
no
Current decrease
(data[count] <
yes
no
Assign max segment peak position
(minSegment[numMinSegments].indexPeak = count-
Positive slope OR
No slope AND Positive
Delayed slope
Positive
slope
yes
no
1
2
3
4
5

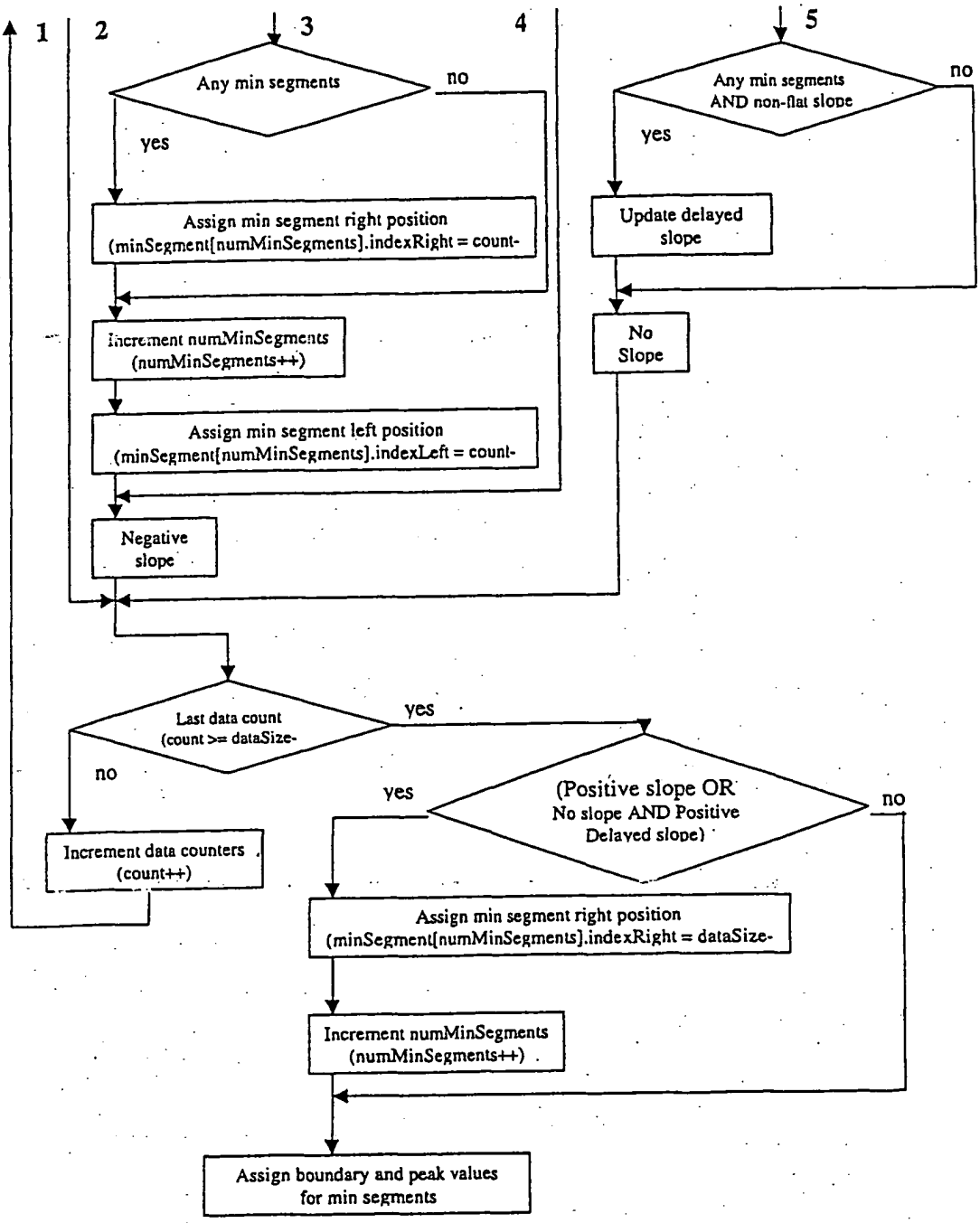

1
2
3
4
5
Any min segments
no
yes
Assign min segment right position
(minSegment[numMinSegments].indexRight = count-
Increment numMinSegments
(numMinSegments++)
Assign min segment left position
(minSegment[numMinSegments].indexLeft = count-
Negative
slope
Any min segments
AND non-flat slope
no
yes
Update delayed
slope
No
Slope
Last data count
(count >= dataSize-
yes
no
Increment data counters
(count++)
yes
(Positive slope OR
No slope AND Positive
Delayed slope)
no
Assign min segment right position
(minSegment[numMinSegments].indexRight = dataSize-
Increment numMinSegments
(numMinSegments++)
Assign boundary and peak values
for min segments

FIG 26 (cont)

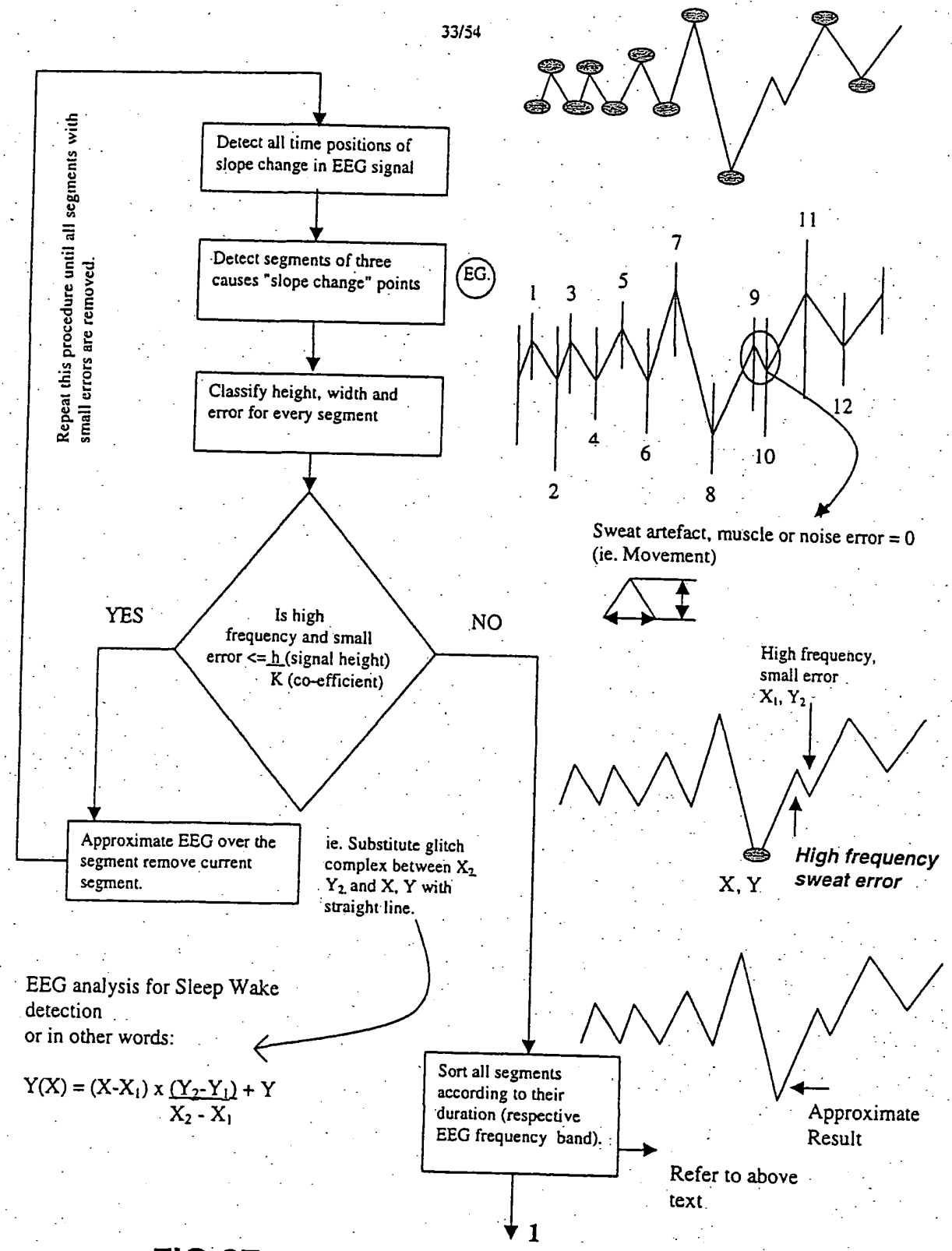
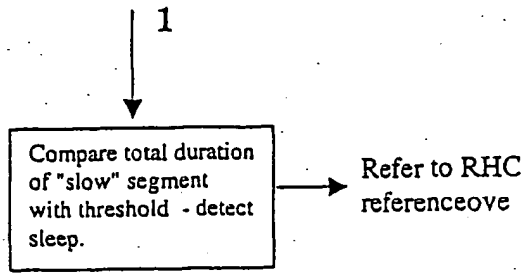
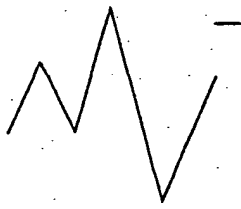

Repeat this procedure until all segments with small errors are removed.
Detect all time positions of slope change in EEG signal
Detect segments of three causes "slope change" points
EG.
Classify height, width and error for every segment
Is high frequency and small error <= h (signal height) K (co-efficient)
YES
NO
Approximate EEG over the segment remove current segment.
ie. Substitute glitch complex between X2, Y2 and X, Y with straight line.
EEG analysis for Sleep Wake detection
or in other words:
Y(X) = (X-X1) x (Y2-Y1) / (X2 - X1) + Y
Sort all segments according to their duration (respective EEG frequency band).
1
1 3 5 7 9 11
2 4 6 8 10 12
Sweat artefact, muscle or noise error = 0
(ie. Movement)
High frequency, small error
X1, Y2
X, Y
High frequency sweat error
Approximate Result
Refer to above text

FIG 27



EG. Note 1. we do not apply glitch element sleep analysis is corrupted due to excessive fast frequency noise or artefact signal corruption (this fast frequency artefact can be created by generation of muscle movement)

Note 2.



IE. Instead of this example being interpreted as alpha it may (due to glitch) be interpreted as beta and generate errors in sleep state assessment.

FIG 27 (cont)

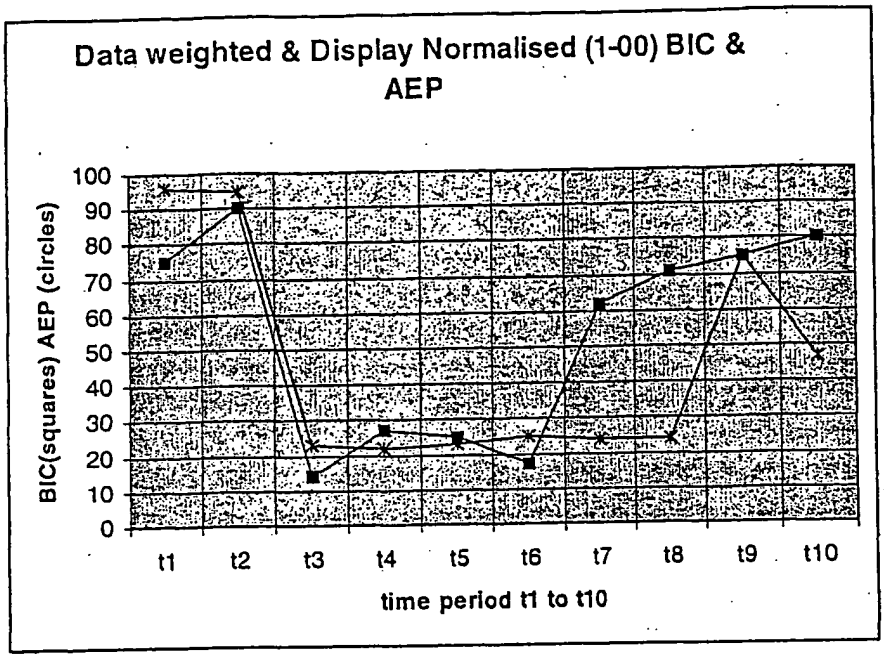

Data weighted & Display Normalised (1-00) BIC & AEP
BIC(squares) AEP (circles)
100
90
80
70
60
50
40
30
20
10
0
t1
t2
t3
t4
t5
t6
t7
t8
t9
t10
time period t1 to t10

FIG 28

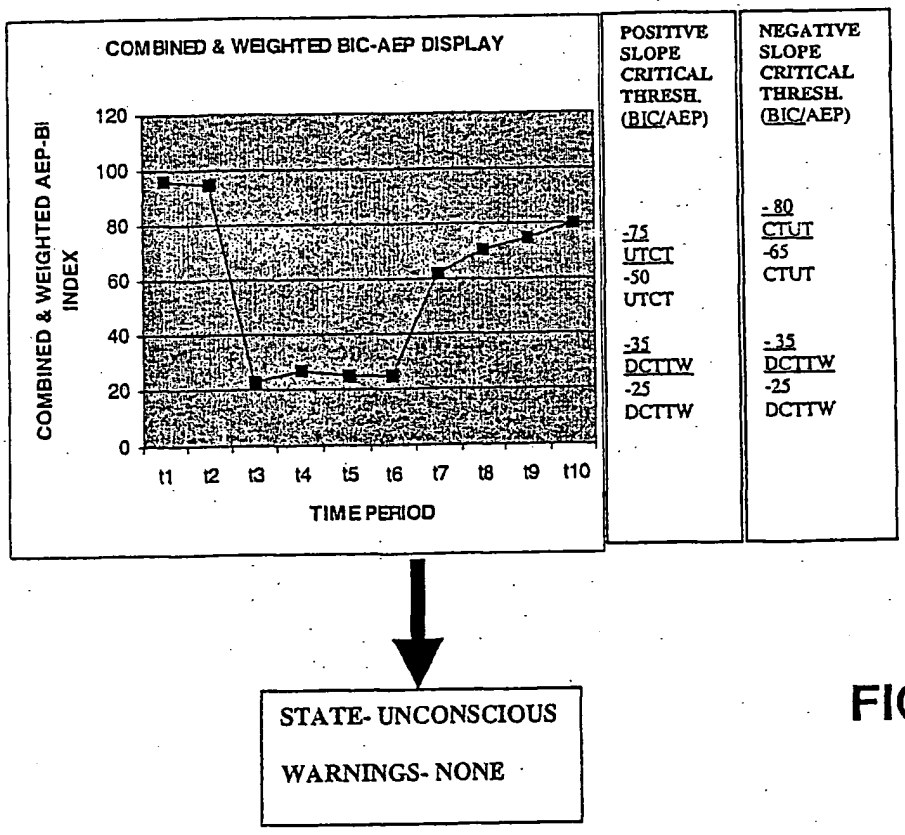

COMBINED & WEIGHTED BIC-AEP DISPLAY
COMBINED & WEIGHTED AEP-BI INDEX
120
100
80
60
40
20
0
t1
t2
t3
t4
t5
t6
t7
t8
t9
t10
TIME PERIOD
POSITIVE SLOPE CRITICAL THRESH. (BIC/AEP)
-75
UTCT
-50
UTCT
-35
DCTTW
-25
DCTTW
NEGATIVE SLOPE CRITICAL THRESH. (BIC/AEP)
- 80
CTUT
-65
CTUT
- 35
DCTTW
-25
DCTTW
STATE- UNCONSCIOUS
WARNINGS- NONE

FIG 29

Input data for S=1, S=2, S=3 .....S=n-1, S=n

Input Analysis Type	S=1 input data
1	26
2	79
3	89
4	56
5	33

Output Data

89

FIG 30A

Input Analysis Type	S=1 input data
1	26
2	33
3	78
4	57
5	30

78

Where S = data sample
S1= data sample 1
Where n= total number of data samples

FIG 30B

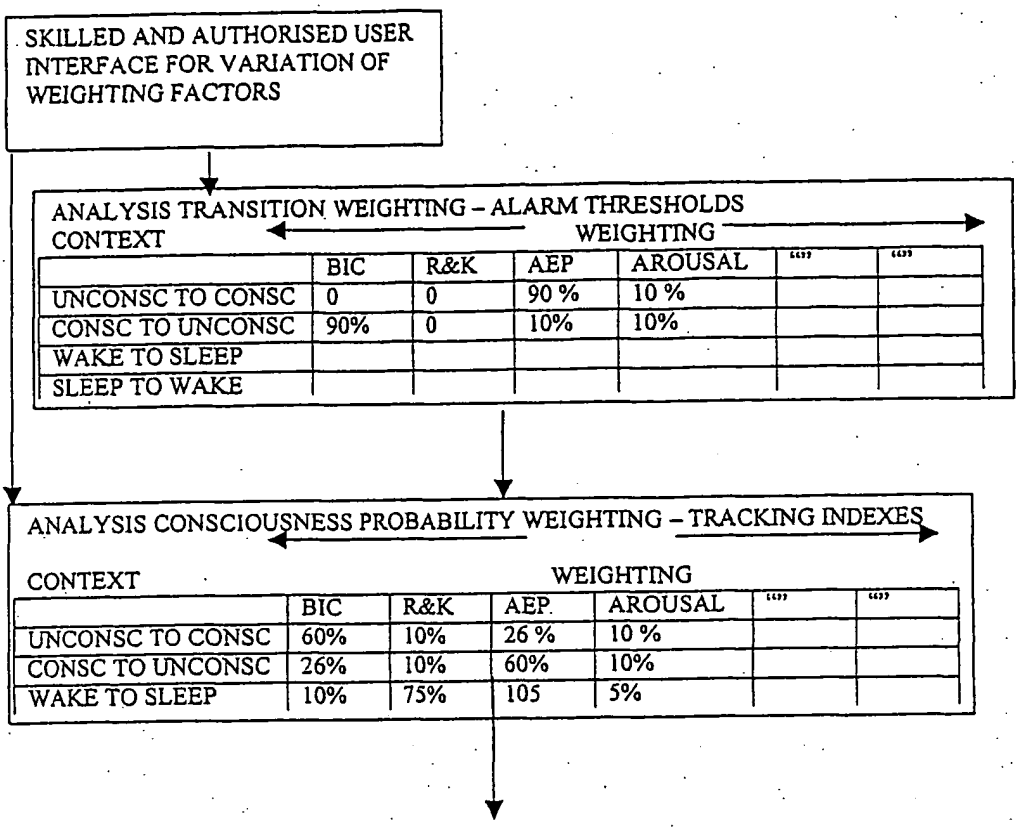

SKILLED AND AUTHORISED USER INTERFACE FOR VARIATION OF WEIGHTING FACTORS
ANALYSIS TRANSITION WEIGHTING – ALARM THRESHOLDS
CONTEXT
WEIGHTING
BIC R&K AEP AROUSAL "" ""
UNCONSC TO CONSC 0 0 90 % 10 %
CONSC TO UNCONSC 90% 0 10% 10%
WAKE TO SLEEP
SLEEP TO WAKE
ANALYSIS CONSCIOUSNESS PROBABILITY WEIGHTING – TRACKING INDEXES
CONTEXT
WEIGHTING
BIC R&K AEP AROUSAL "" ""
UNCONSC TO CONSC 60% 10% 26 % 10 %
CONSC TO UNCONSC 26% 10% 60% 10%
WAKE TO SLEEP 10% 75% 105 5%

FIG 31

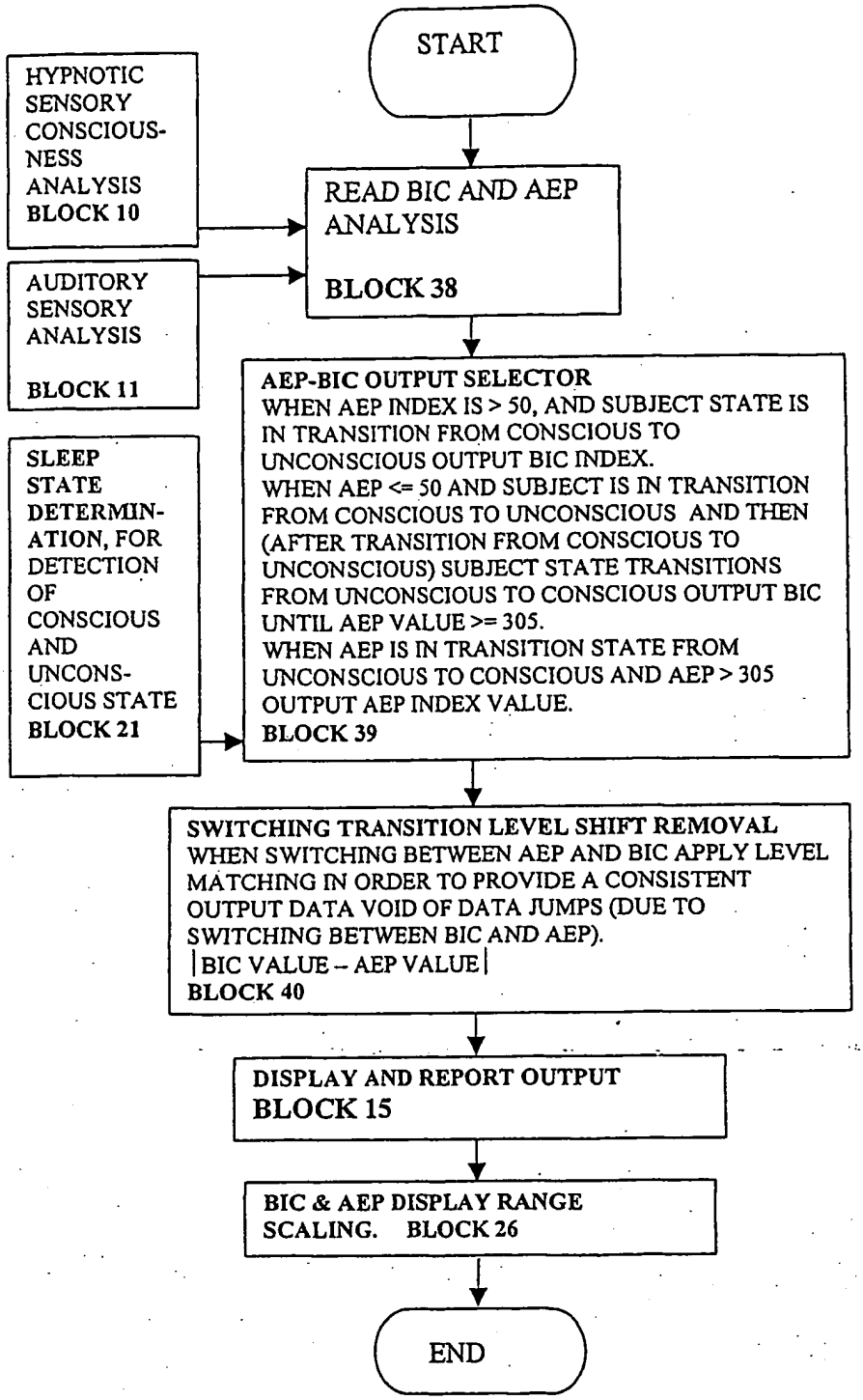

START
HYPNOTIC SENSORY CONSCIOUS-NESS ANALYSIS BLOCK 10
AUDITORY SENSORY ANALYSIS BLOCK 11
SLEEP STATE DETERMIN-ATION, FOR DETECTION OF CONSCIOUS AND UNCONS-CIOUS STATE BLOCK 21
READ BIC AND AEP ANALYSIS BLOCK 38
AEP-BIC OUTPUT SELECTOR
WHEN AEP INDEX IS > 50, AND SUBJECT STATE IS IN TRANSITION FROM CONSCIOUS TO UNCONSCIOUS OUTPUT BIC INDEX.
WHEN AEP <= 50 AND SUBJECT IS IN TRANSITION FROM CONSCIOUS TO UNCONSCIOUS AND THEN (AFTER TRANSITION FROM CONSCIOUS TO UNCONSCIOUS) SUBJECT STATE TRANSITIONS FROM UNCONSCIOUS TO CONSCIOUS OUTPUT BIC UNTIL AEP VALUE >= 305.
WHEN AEP IS IN TRANSITION STATE FROM UNCONSCIOUS TO CONSCIOUS AND AEP > 305 OUTPUT AEP INDEX VALUE.
BLOCK 39
SWITCHING TRANSITION LEVEL SHIFT REMOVAL
WHEN SWITCHING BETWEEN AEP AND BIC APPLY LEVEL MATCHING IN ORDER TO PROVIDE A CONSISTENT OUTPUT DATA VOID OF DATA JUMPS (DUE TO SWITCHING BETWEEN BIC AND AEP).
|BIC VALUE – AEP VALUE|
BLOCK 40
DISPLAY AND REPORT OUTPUT BLOCK 15
BIC & AEP DISPLAY RANGE SCALING. BLOCK 26
END

FIG 32

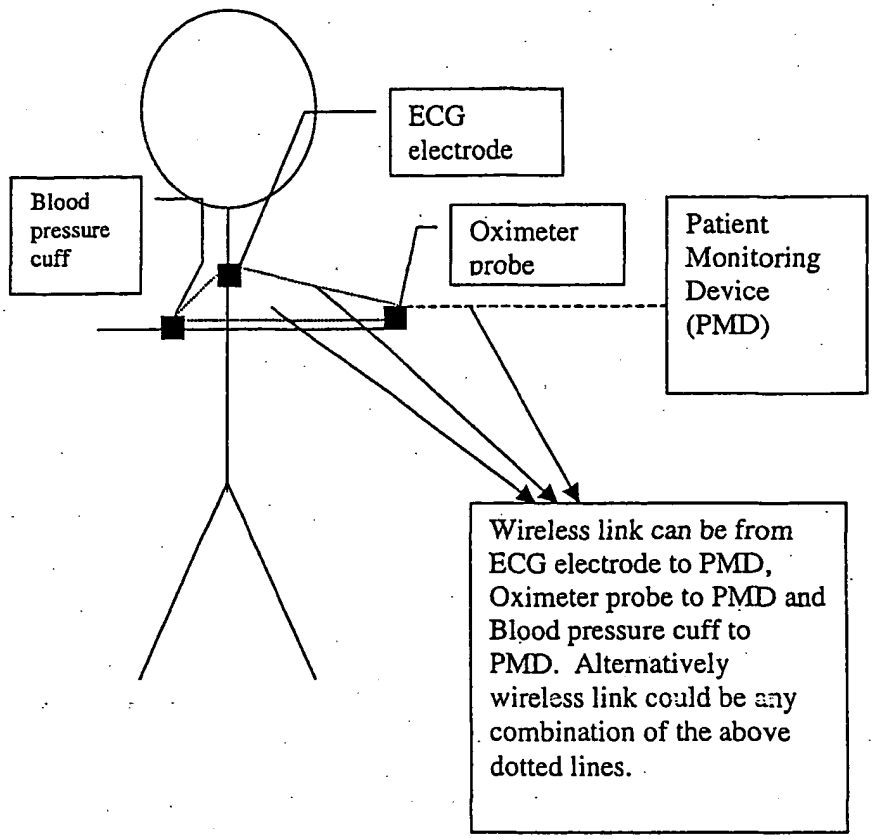

ECG electrode
Blood pressure cuff
Oximeter probe
Patient Monitoring Device (PMD)
Wireless link can be from ECG electrode to PMD, Oximeter probe to PMD and Blood pressure cuff to PMD. Alternatively wireless link could be any combination of the above dotted lines.

FIG 33

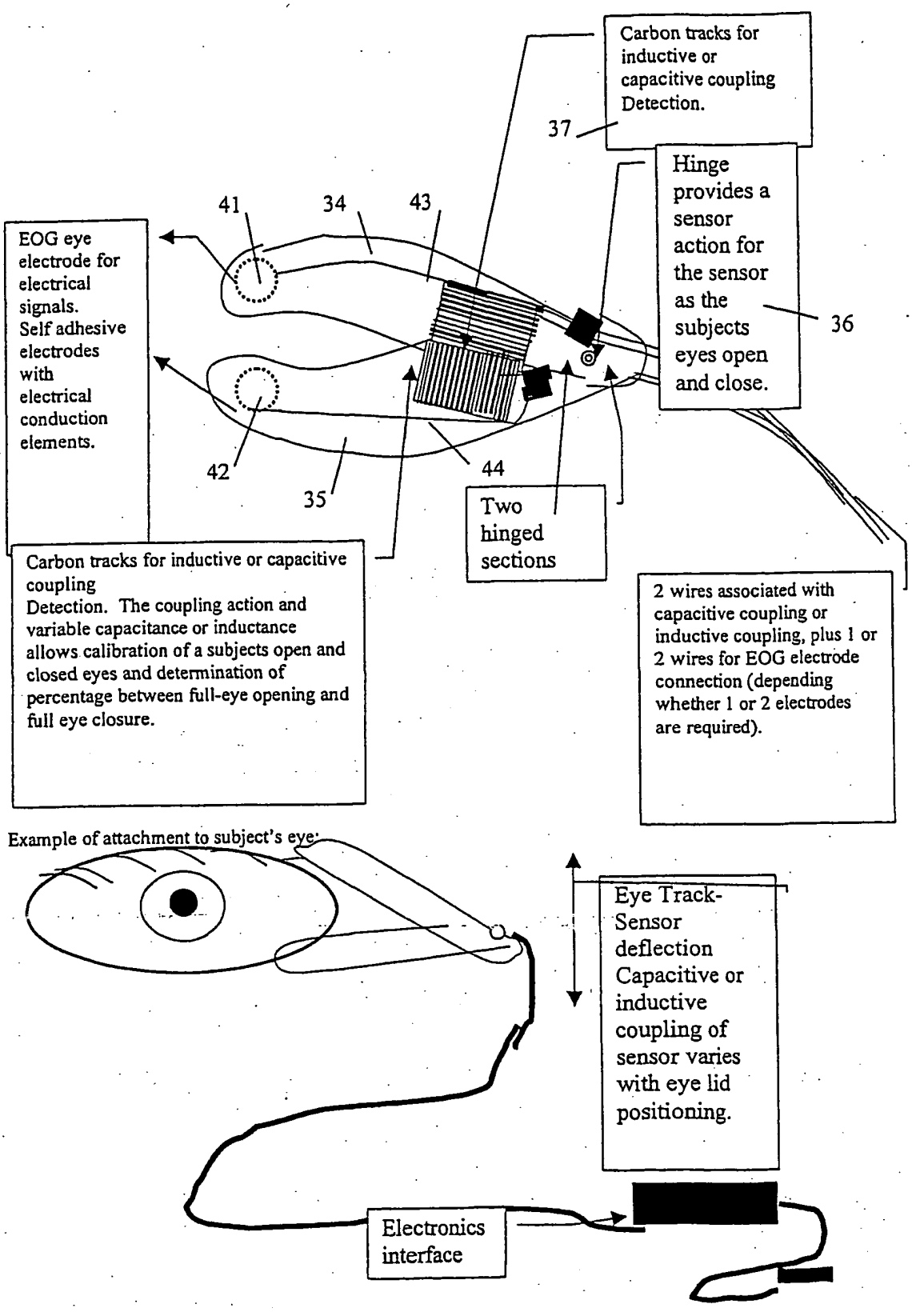

Carbon tracks for inductive or capacitive coupling Detection.
37
Hinge provides a sensor action for the sensor as the subjects eyes open and close.
36
41
34
43
EOG eye electrode for electrical signals. Self adhesive electrodes with electrical conduction elements.
42
35
44
Two hinged sections
Carbon tracks for inductive or capacitive coupling
Detection. The coupling action and variable capacitance or inductance allows calibration of a subjects open and closed eyes and determination of percentage between full-eye opening and full eye closure.
2 wires associated with capacitive coupling or inductive coupling, plus 1 or 2 wires for EOG electrode connection (depending whether 1 or 2 electrodes are required).
Example of attachment to subject's eye
Eye Track-Sensor deflection Capacitive or inductive coupling of sensor varies with eye lid positioning.
Electronics interface

FIG 34A

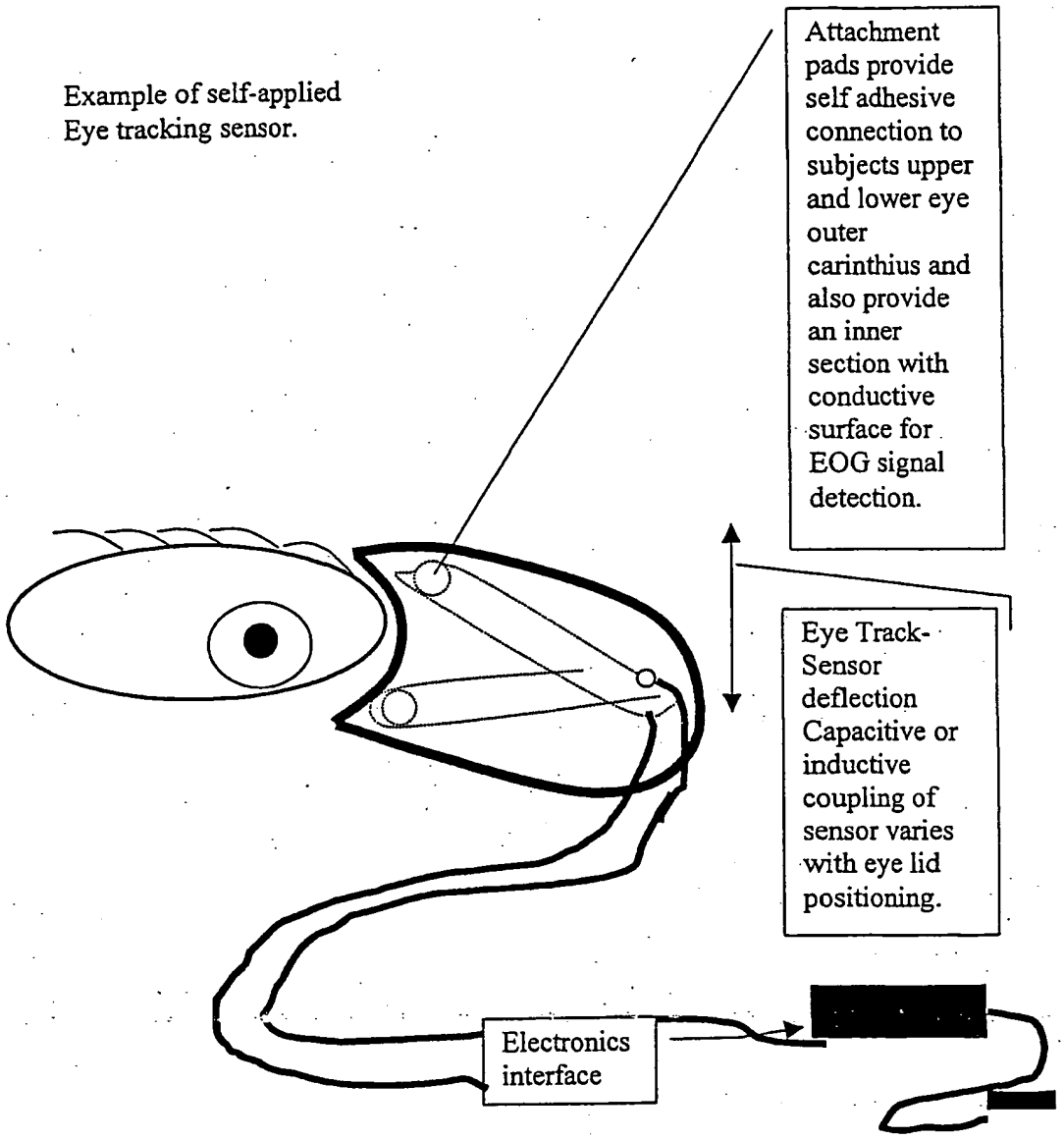

Example of self-applied
Eye tracking sensor.
Attachment pads provide self adhesive connection to subjects upper and lower eye outer carinthius and also provide an inner section with conductive surface for EOG signal detection.
Eye Track-Sensor deflection Capacitive or inductive coupling of sensor varies with eye lid positioning.
Electronics interface

FIG 34A (cont)

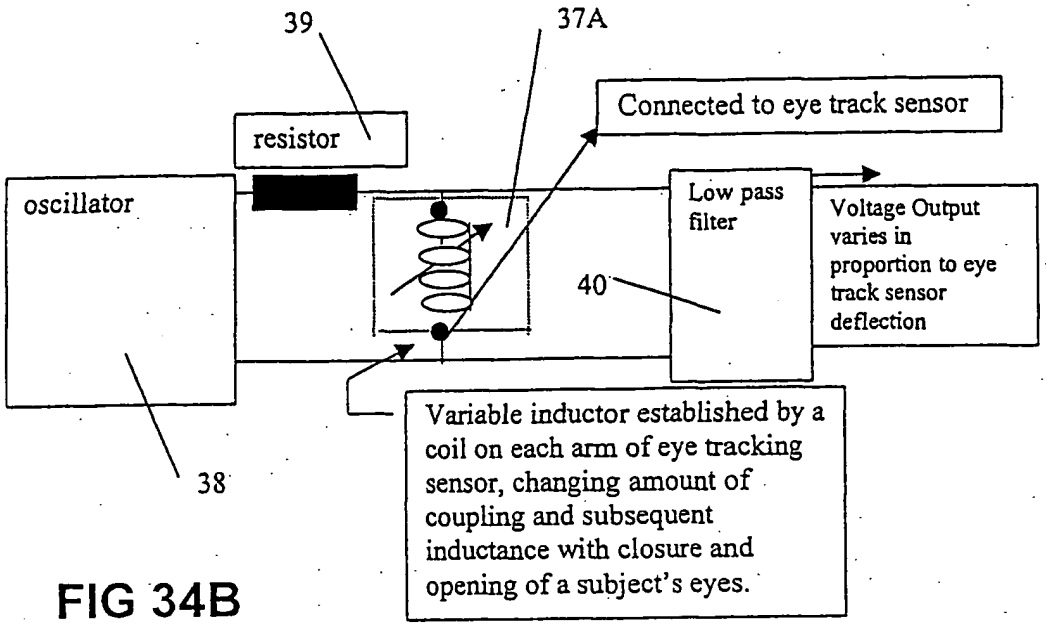


FIG 34B

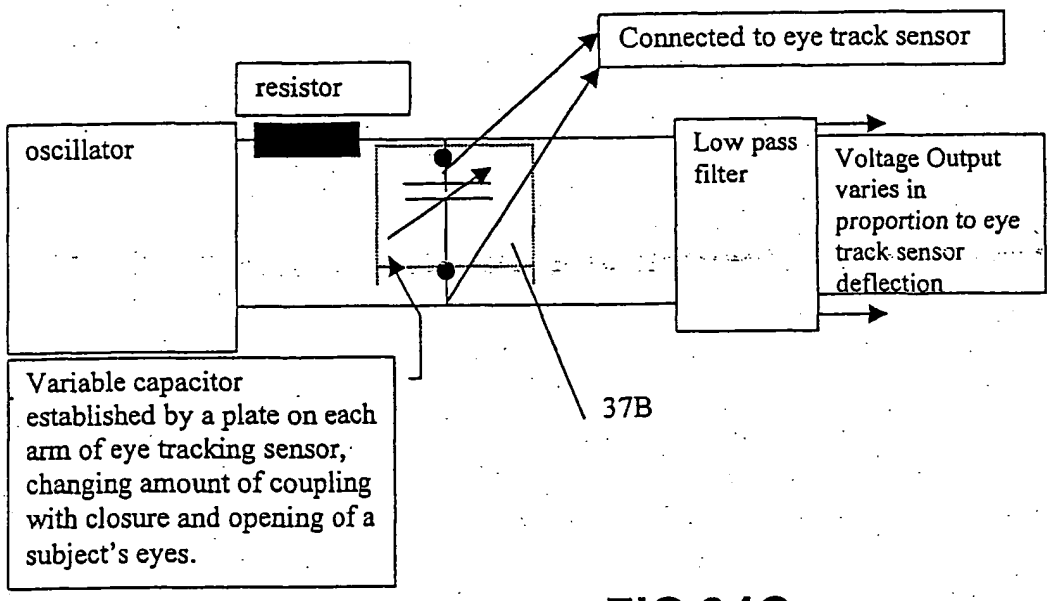


FIG 34C

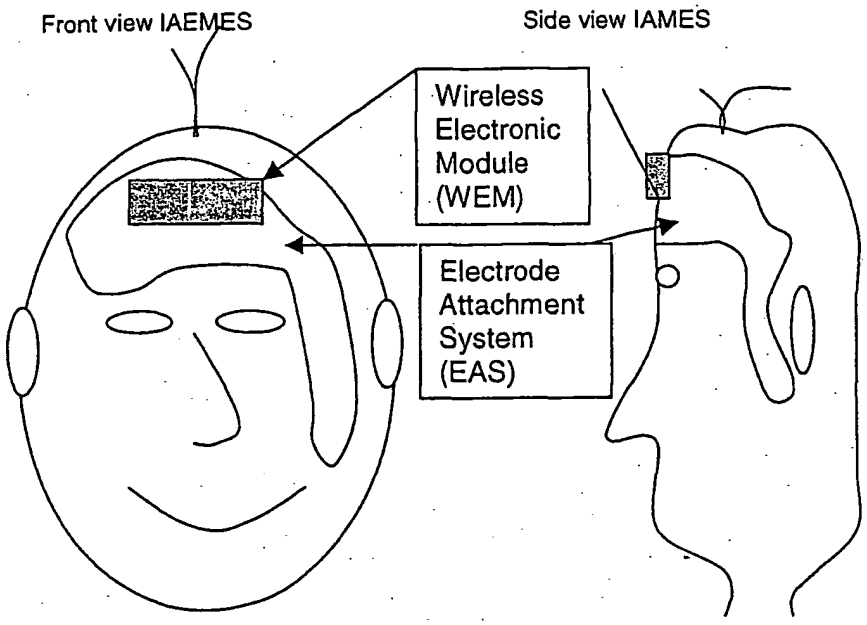

Front view IAEMES
Side view IAMES
Wireless Electronic Module (WEM)
Electrode Attachment System (EAS)

FIG 35

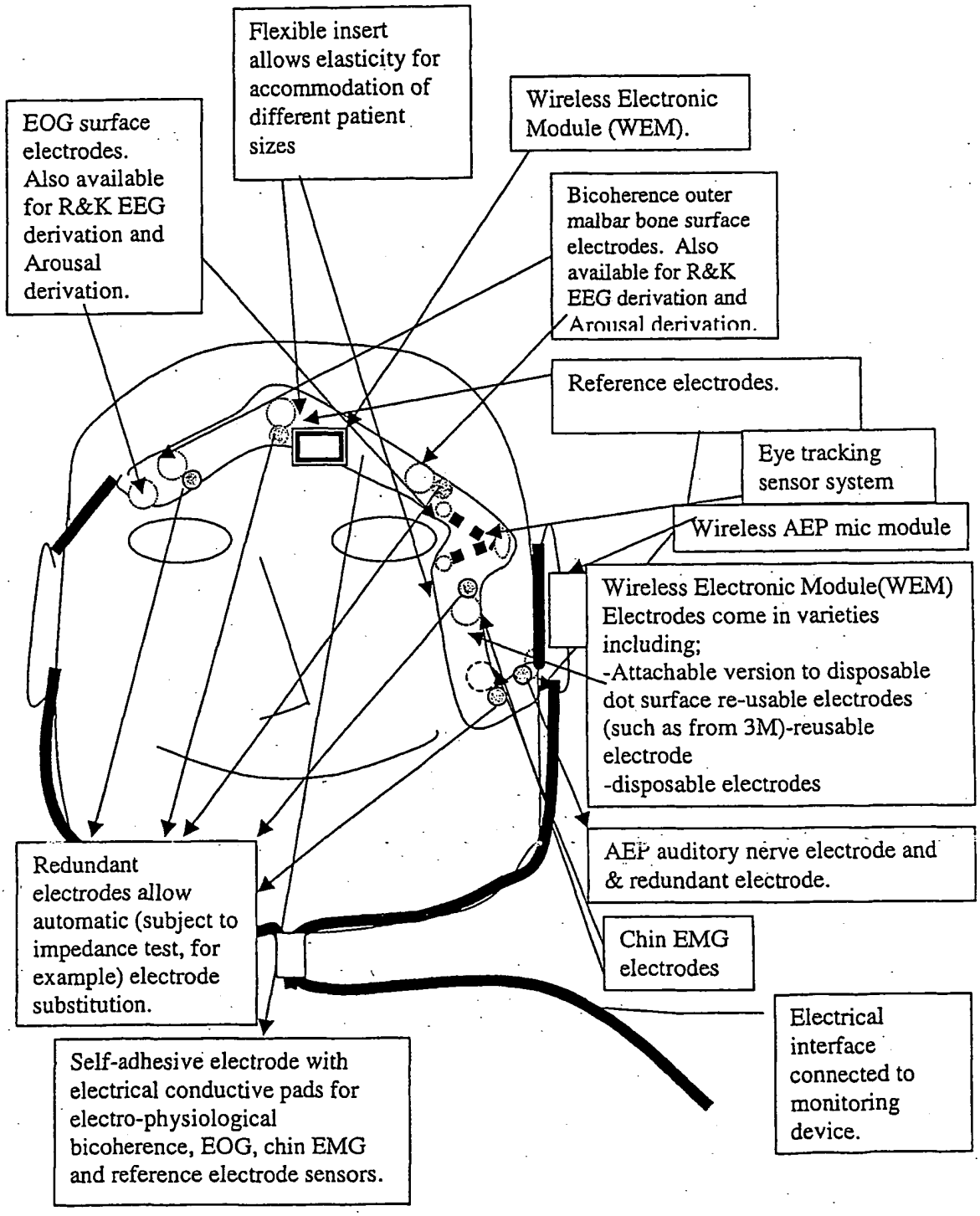

Flexible insert allows elasticity for accommodation of different patient sizes
Wireless Electronic Module (WEM).
EOG surface electrodes. Also available for R&K EEG derivation and Arousal derivation.
Bicoherence outer malbar bone surface electrodes. Also available for R&K EEG derivation and Arousal derivation.
Reference electrodes.
Eye tracking sensor system
Wireless AEP mic module
Wireless Electronic Module(WEM) Electrodes come in varieties including;
-Attachable version to disposable dot surface re-usable electrodes (such as from 3M)-reusable electrode
-disposable electrodes
AEP auditory nerve electrode and & redundant electrode.
Chin EMG electrodes
Redundant electrodes allow automatic (subject to impedance test, for example) electrode substitution.
Electrical interface connected to monitoring device.
Self-adhesive electrode with electrical conductive pads for electro-physiological bicoherence, EOG, chin EMG and reference electrode sensors.

FIG 36

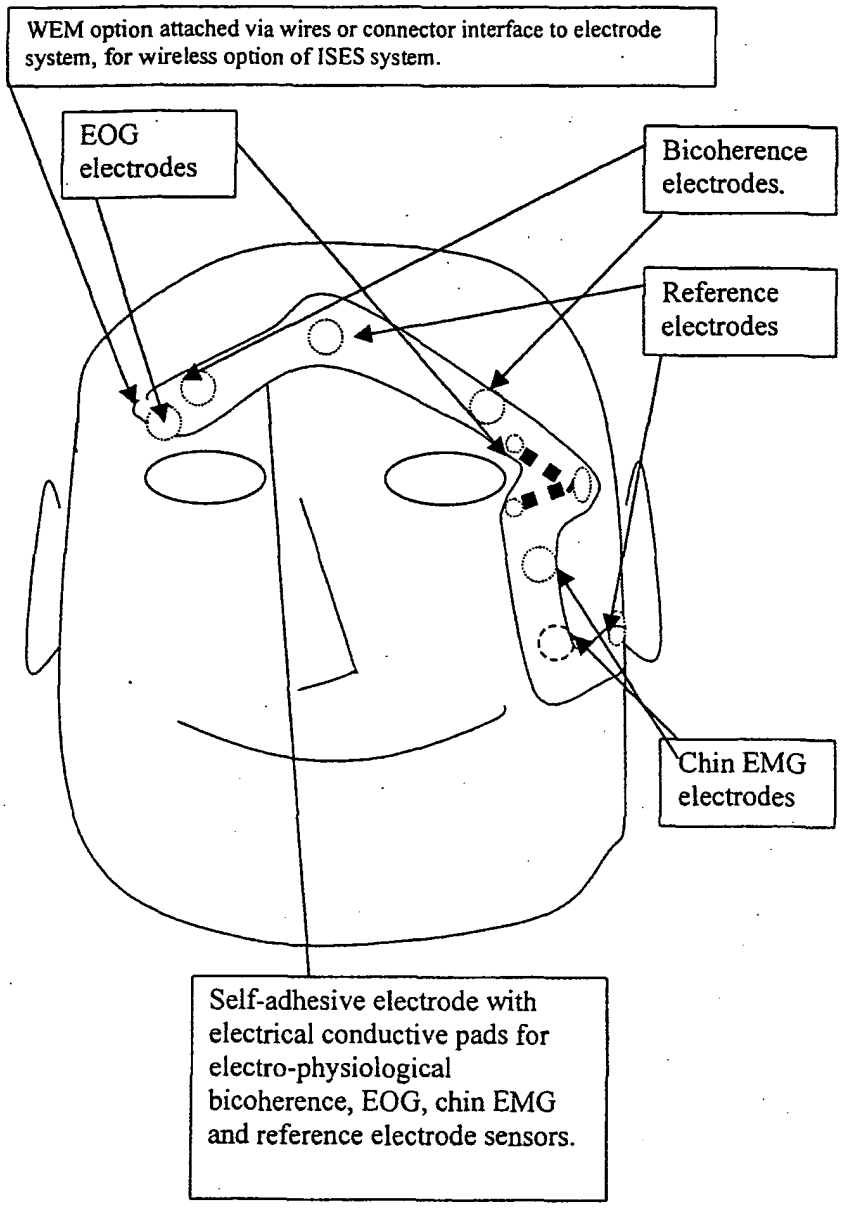

WEM option attached via wires or connector interface to electrode system, for wireless option of ISES system.
EOG electrodes
Bicoherence electrodes.
Reference electrodes
Chin EMG electrodes
Self-adhesive electrode with electrical conductive pads for electro-physiological bicoherence, EOG, chin EMG and reference electrode sensors.

FIG 37

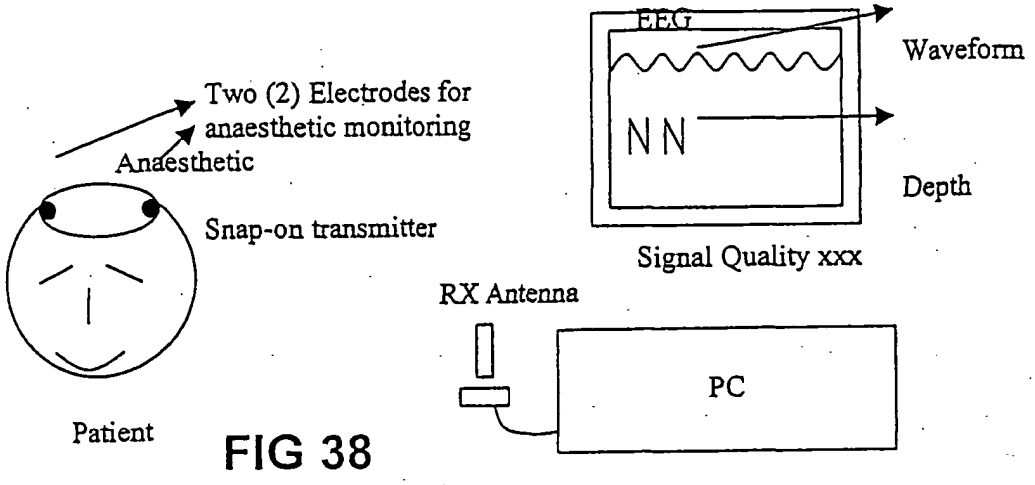
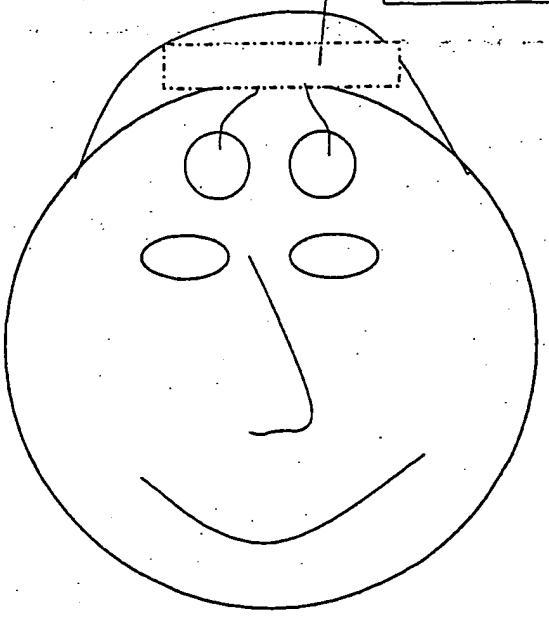


FIG 38

Version where active electrode is positioned via very short wires to a convenient location point such as under a head cap or other.

Wireless module with in-direct attach format where wireless module attaches via small wires and press-stud, clip or slide in type connection formats direct to or electrode substrate or electrodes, which are in attached to patient. In this format the in-direct attachment provides increased interference dure to longer interconnecting wire distances.

FIG 46



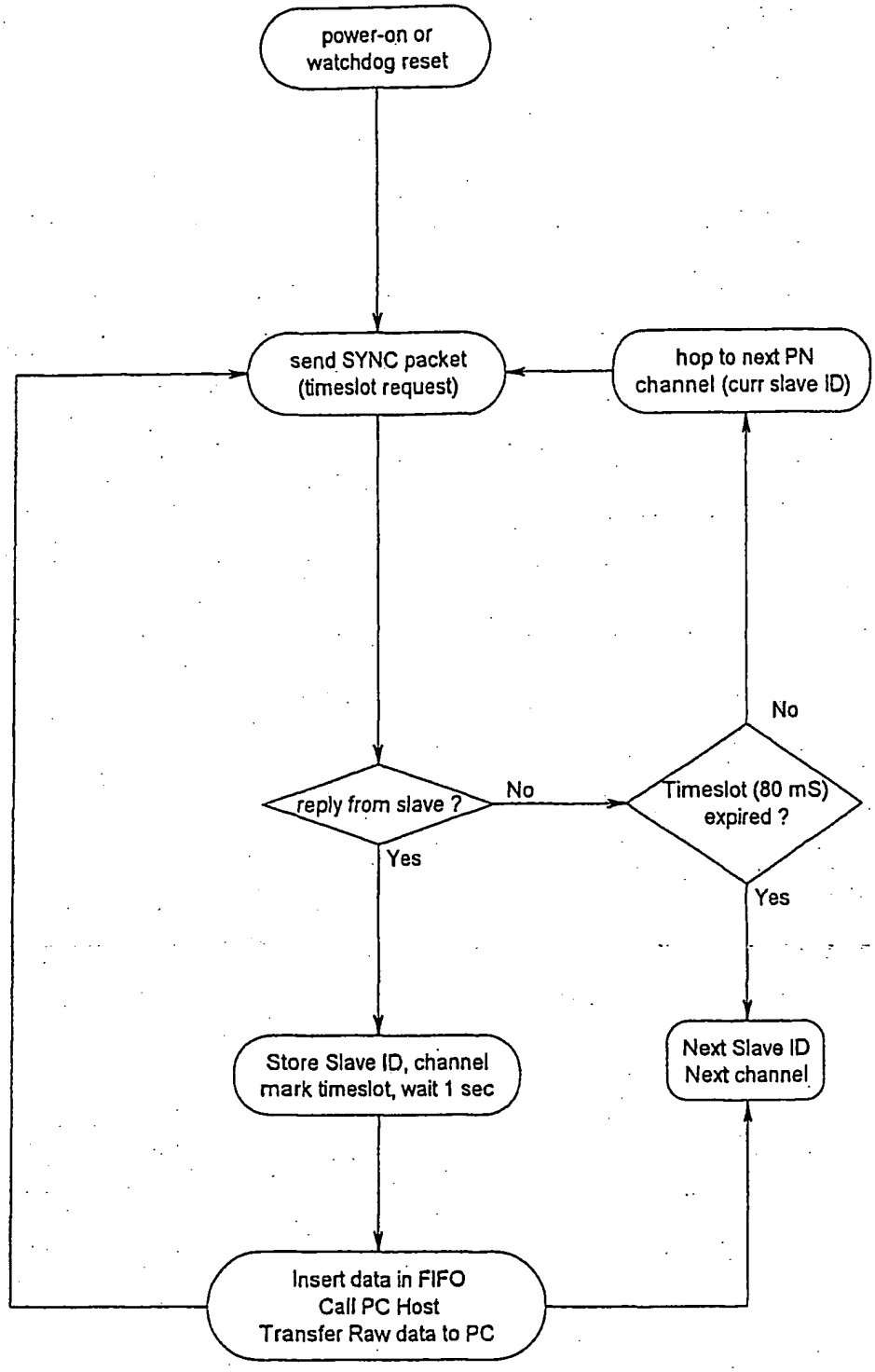

power-on or
watchdog reset
send SYNC packet
(timeslot request)
hop to next PN
channel (curr slave ID)
reply from slave ?
No
Timeslot (80 mS)
expired ?
No
Yes
Yes
Store Slave ID, channel
mark timeslot, wait 1 sec
Next Slave ID
Next channel
Insert data in FIFO
Call PC Host
Transfer Raw data to PC

FIG 39

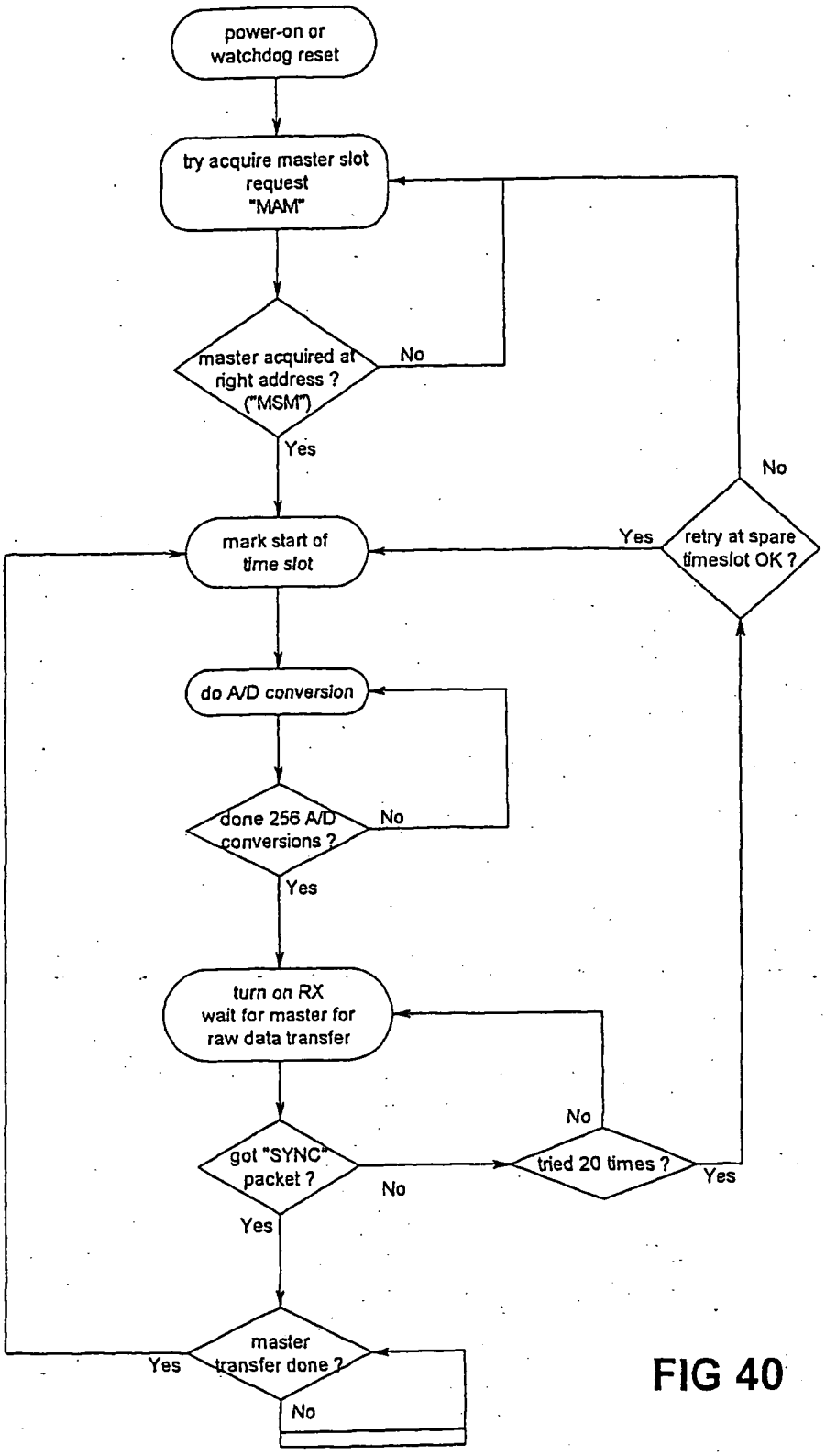

power-on or watchdog reset
try acquire master slot request "MAM"
master acquired at right address ? ("MSM")
No
Yes
mark start of time slot
do A/D conversion
done 256 A/D conversions ?
No
Yes
turn on RX wait for master for raw data transfer
got "SYNC" packet ?
No
Yes
tried 20 times ?
No
Yes
retry at spare timeslot OK ?
No
Yes
master transfer done ?
Yes
No

FIG 40

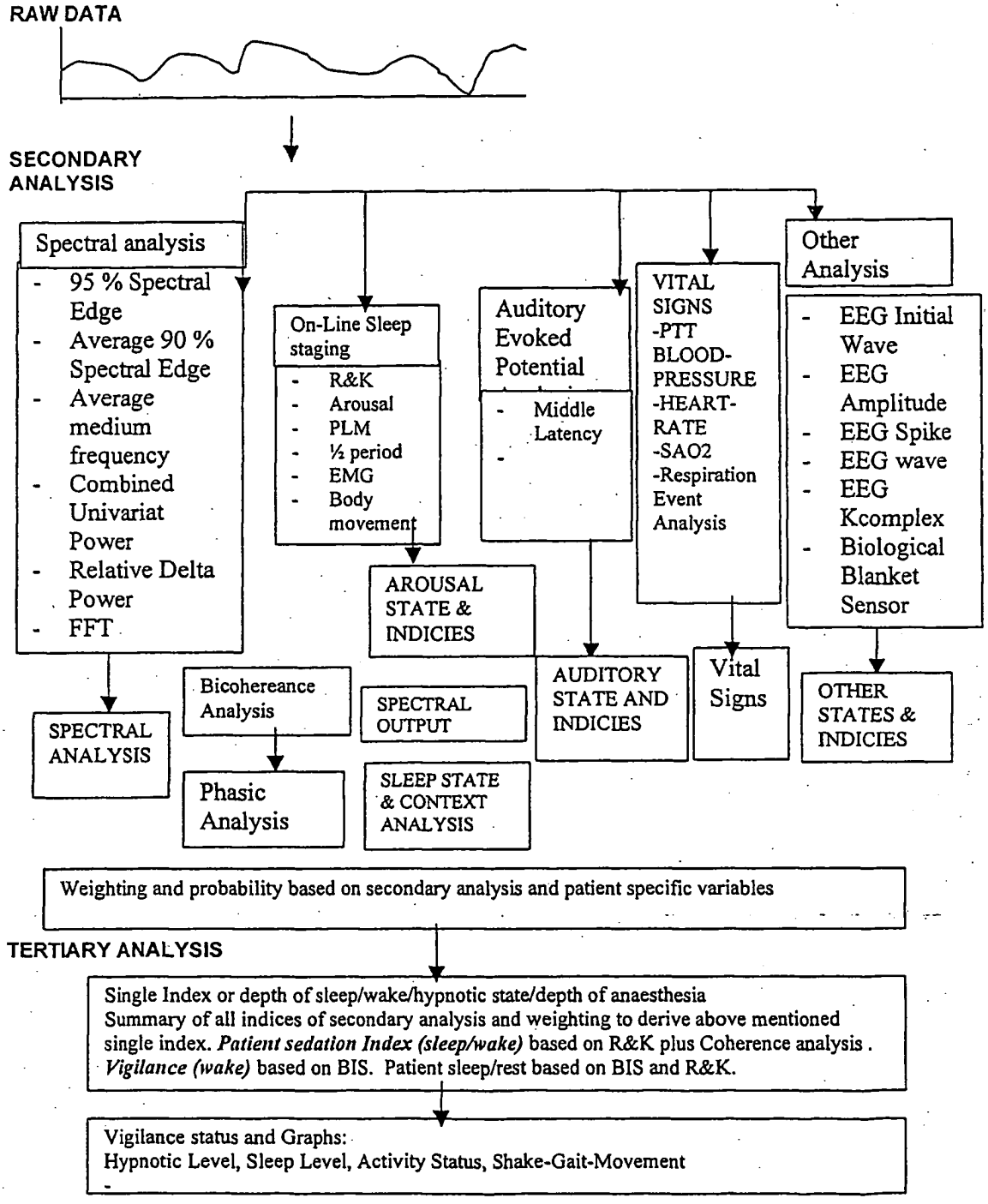

RAW DATA
SECONDARY ANALYSIS
Spectral analysis
- 95 % Spectral Edge
- Average 90 % Spectral Edge
- Average medium frequency
- Combined Univariat Power
- Relative Delta Power
- FFT
On-Line Sleep staging
- R&K
- Arousal
- PLM
- ½ period
- EMG
- Body movement
Auditory Evoked Potential
- Middle Latency
-
VITAL SIGNS
-PTT
BLOOD-PRESSURE
-HEART-RATE
-SAO2
-Respiration
Event Analysis
Other Analysis
- EEG Initial Wave
- EEG Amplitude
- EEG Spike
- EEG wave
- EEG Kcomplex
- Biological Blanket Sensor
AROUSAL STATE & INDICIES
SPECTRAL ANALYSIS
Bicohereance Analysis
SPECTRAL OUTPUT
AUDITORY STATE AND INDICIES
Vital Signs
OTHER STATES & INDICIES
Phasic Analysis
SLEEP STATE & CONTEXT ANALYSIS
Weighting and probability based on secondary analysis and patient specific variables
TERTIARY ANALYSIS
Single Index or depth of sleep/wake/hypnotic state/depth of anaesthesia
Summary of all indices of secondary analysis and weighting to derive above mentioned single index. Patient sedation Index (sleep/wake) based on R&K plus Coherence analysis . Vigilance (wake) based on BIS. Patient sleep/rest based on BIS and R&K.
Vigilance status and Graphs:
Hypnotic Level, Sleep Level, Activity Status, Shake-Gait-Movement

FIG 41

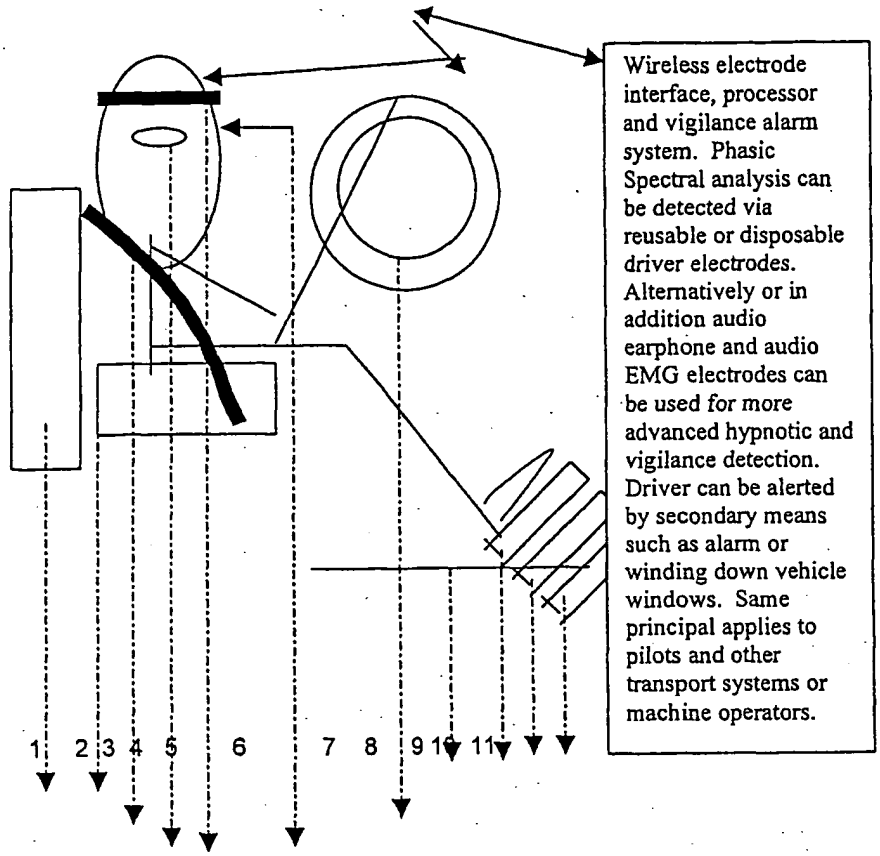

Wireless electrode interface, processor and vigilance alarm system. Phasic Spectral analysis can be detected via reusable or disposable driver electrodes. Alternatively or in addition audio earphone and audio EMG electrodes can be used for more advanced hypnotic and vigilance detection. Driver can be alerted by secondary means such as alarm or winding down vehicle windows. Same principal applies to pilots and other transport systems or machine operators.
1
2
3
4
5
6
7
8
9
10
11

FIG 42

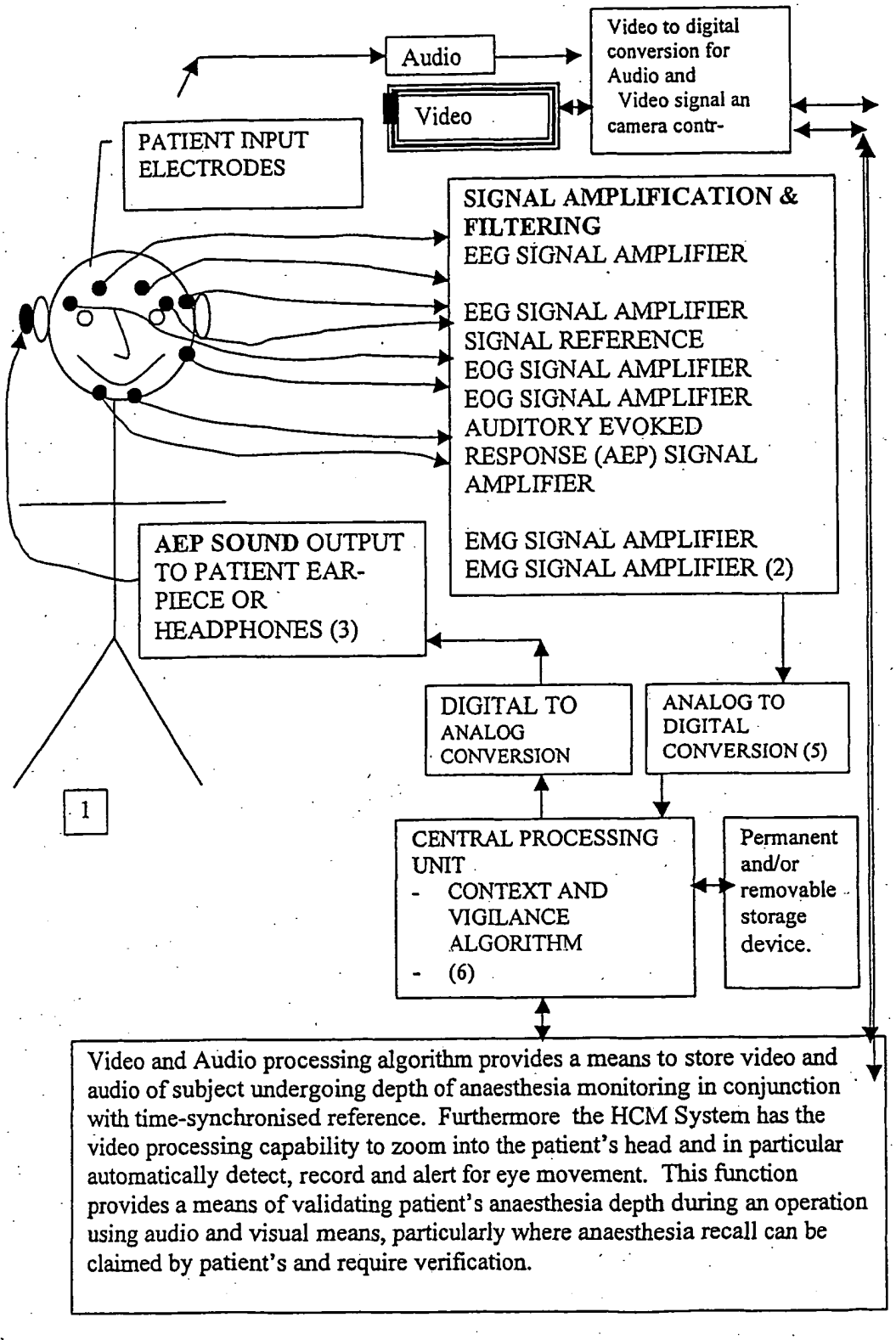

Audio
Video
Video to digital conversion for Audio and Video signal an camera contr-
PATIENT INPUT ELECTRODES
SIGNAL AMPLIFICATION & FILTERING
EEG SIGNAL AMPLIFIER
EEG SIGNAL AMPLIFIER
SIGNAL REFERENCE
EOG SIGNAL AMPLIFIER
EOG SIGNAL AMPLIFIER
AUDITORY EVOKED RESPONSE (AEP) SIGNAL AMPLIFIER
EMG SIGNAL AMPLIFIER
EMG SIGNAL AMPLIFIER (2)
AEP SOUND OUTPUT TO PATIENT EAR-PIECE OR HEADPHONES (3)
DIGITAL TO ANALOG CONVERSION
ANALOG TO DIGITAL CONVERSION (5)
1
CENTRAL PROCESSING UNIT
- CONTEXT AND VIGILANCE ALGORITHM
- (6)
Permanent and/or removable storage device.
Video and Audio processing algorithm provides a means to store video and audio of subject undergoing depth of anaesthesia monitoring in conjunction with time-synchronised reference. Furthermore the HCM System has the video processing capability to zoom into the patient's head and in particular automatically detect, record and alert for eye movement. This function provides a means of validating patient's anaesthesia depth during an operation using audio and visual means, particularly where anaesthesia recall can be claimed by patient's and require verification.

FIG 43

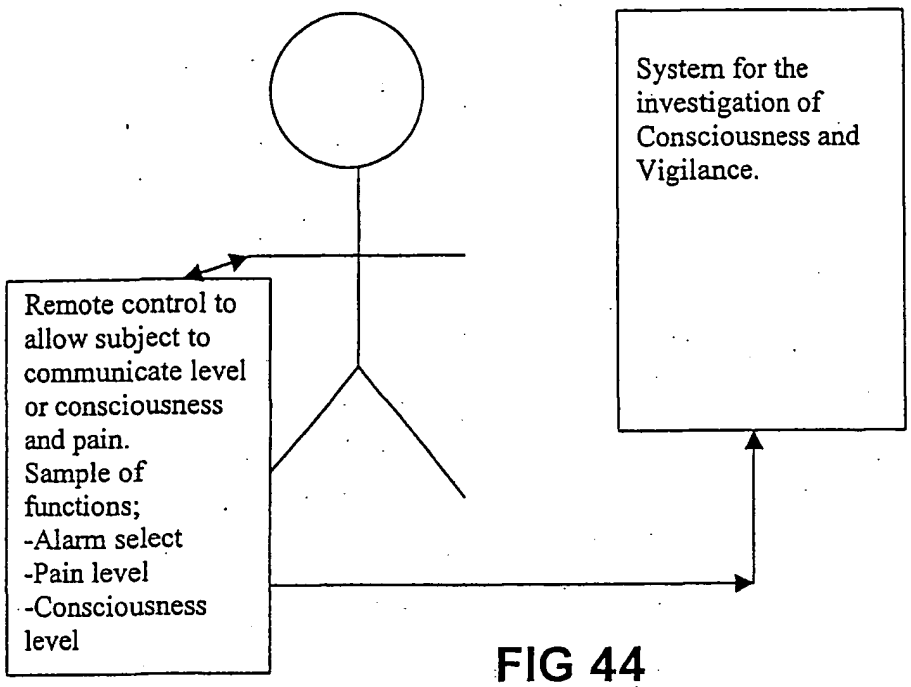

System for the investigation of Consciousness and Vigilance.
Remote control to allow subject to communicate level or consciousness and pain.
Sample of functions;
-Alarm select
-Pain level
-Consciousness level

FIG 44

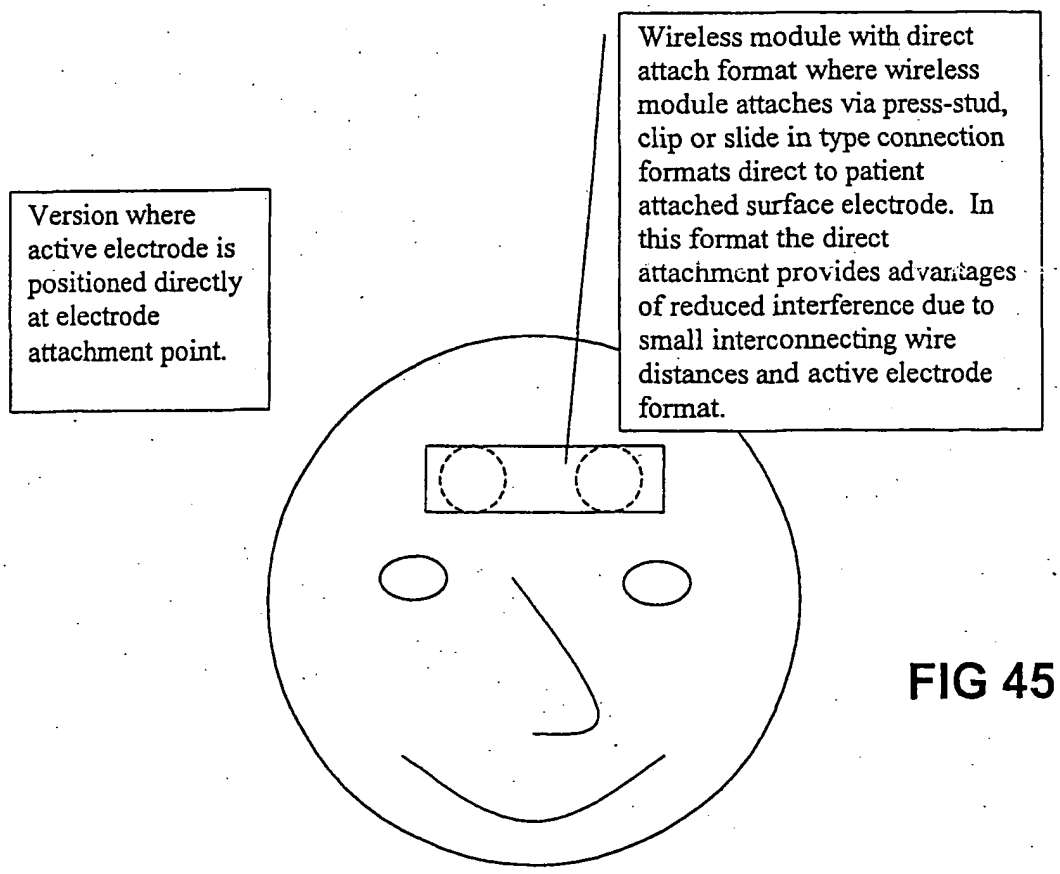
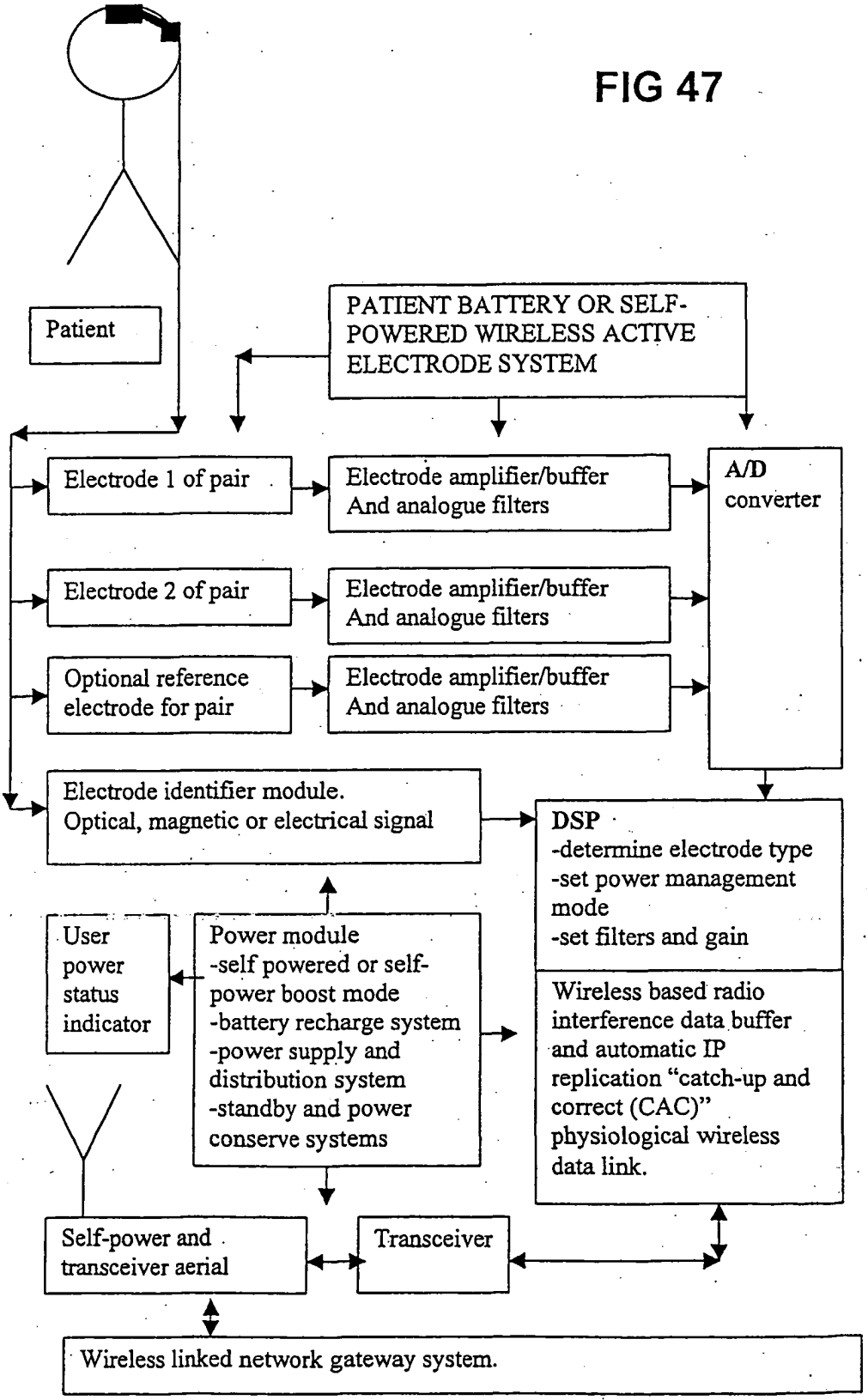

Wireless module with direct attach format where wireless module attaches via press-stud, clip or slide in type connection formats direct to patient attached surface electrode. In this format the direct attachment provides advantages of reduced interference due to small interconnecting wire distances and active electrode format.
Version where active electrode is positioned directly at electrode attachment point.

FIG 45

FIG 47


Patient
PATIENT BATTERY OR SELF-POWERED WIRELESS ACTIVE ELECTRODE SYSTEM
Electrode 1 of pair
Electrode amplifier/buffer And analogue filters
A/D converter
Electrode 2 of pair
Electrode amplifier/buffer And analogue filters
Optional reference electrode for pair
Electrode amplifier/buffer And analogue filters
Electrode identifier module. Optical, magnetic or electrical signal
DSP
-determine electrode type
-set power management mode
-set filters and gain
User power status indicator
Power module
-self powered or self-power boost mode
-battery recharge system
-power supply and distribution system
-standby and power conserve systems
Wireless based radio interference data buffer and automatic IP replication "catch-up and correct (CAC)" physiological wireless data link.
Self-power and transceiver aerial
Transceiver
Wireless linked network gateway system.

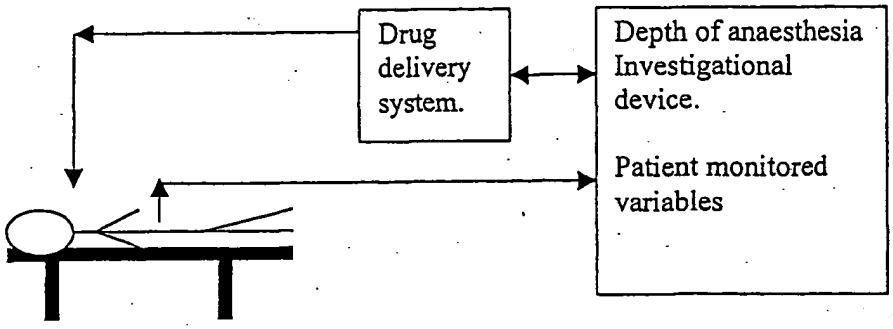

Drug
delivery
system.
Depth of anaesthesia
Investigational
device.
Patient monitored
variables

FIG 48

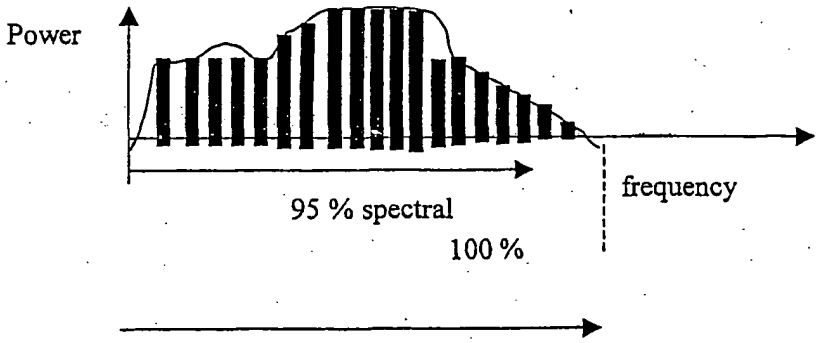

Power
95 % spectral
100 %
frequency

FIG 49